

US3022103 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:53:37

All time stamps listed in this document are displayed in GMT

US3022103

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 16:54:59

Generated On: 09 Jun 2021 14:53:37

Participant ID

US3022103

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

US3022103

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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 16:55:31

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Date of Birth (MMM yyyy)	(b) (6) 1960
Age	59
Age Units	YEARS
Age (Derived)	59
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 16:55:31

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Date of Informed Consent (*dd MMM yyyy*) 31 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 16:55:31

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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 16:55:31

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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 16:55:31

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Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2003
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Condition	BILATERAL ONYCHOMYCOSIS
Start date (dd MMM yyyy)	UN UNK 2018
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 2018
Start Year (derived)	2018
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Condition	POST MENOPAUSAL
Start date (dd MMM yyyy)	UN UNK 2010
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 2010
Start Year (derived)	2010
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 16:55:31

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Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	31 JUL 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 15:05
Height (xxx.x)	163.5 cm
Weight (xxx.x)	63.9 kg
BMI (xxx.x)	23.90371 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 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 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 16:55:31

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Date of assessment (*dd MMM yyyy*) 31 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 2010

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 16:55:31

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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 16:55:31

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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	LIVES IN COMMUNITY WITH ONGOING PERSON TO PERSON TRANSMISSION

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 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 16:55:31

Generated On: 09 Jun 2021 14:53:37

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 100470

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 16:55:32

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Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

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)	31 JUL 2020
Time of assessment (00:00-23:59)	15:05 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 15:05
Temperature (xxx.x)	98.5 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

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)	31 JUL 2020
Time of assessment (00:00-23:59)	16:56 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 16:56
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	108 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 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 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 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 16:55:31

Generated On: 09 Jun 2021 14:53:37

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) 31 JUL 2020

What was the treatment time? (00:00-23:59) 16:20 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 16:20

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 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	16:02 (24 HR)
Collection date and time (derived)	31 JUL 2020 16:02

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Collection date (dd MMM yyyy)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:35	31 JUL 2020 15:35
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 16:53

PC Open Date & Time

31 JUL 2020 16:40

PC Close Date & Time

31 JUL 2020 19:10

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.7 °F

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

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

PC Time Stamp	31 JUL 2020 20:13
PC Open Date & Time	31 JUL 2020 20:05
PC Close Date & Time	01 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

99.2 °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

01 AUG 2020 18:28

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

99.1 °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 19:14

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

03 AUG 2020 21:39

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 21:15

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

97.9 °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

05 AUG 2020 18:57

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

96.9 °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

06 AUG 2020 19:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

31 JUL 2020 16:54

PC Open Date & Time

31 JUL 2020 16:40

PC Close Date & Time

31 JUL 2020 19:10

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

31 JUL 2020 20:13

PC Open Date & Time

31 JUL 2020 20:05

PC Close Date & Time

01 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

01 AUG 2020 18:30

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

02 AUG 2020 19:15

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

03 AUG 2020 21:40

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

04 AUG 2020 21:15

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

05 AUG 2020 18:58

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

06 AUG 2020 19:00

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 16:55
PC Open Date & Time	31 JUL 2020 16:40
PC Close Date & Time	31 JUL 2020 19:10

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

No ☒

Yes ☐

PC Time stamp 31 JUL 2020 20:14

PC Open Date & Time 31 JUL 2020 20:05

PC Close Date & Time 01 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

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 ☒

PRODUCTION RELEASE (v12.003

45 of 2061

EAB) (1725)

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 18:31
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

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 ☒

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 19:15
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

49 of 2061

EAB) (1725)

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 21:40
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

51 of 2061

EAB) (1725)

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 21:15
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

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)

53 of 2061

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 18:58
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

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 ☒

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 19:01
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3022103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 10 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3022103

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 17 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3022103

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3022103

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

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)	23 NOV 2020
Time of assessment (00:00-23:59)	10:25 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 10:25
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)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

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)	23 NOV 2020
Time of assessment (00:00-23:59)	12:34 (24 HR)
Vital Signs Date and Time (derived)	23 NOV 2020 12:34
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

US3022103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

23 NOV 2020

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

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

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) 23 NOV 2020

What was the treatment time? (00:00-23:59) 12:04 (24 HR)

Treatment Date and Time (derived) 23 NOV 2020 12:04

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

US3022103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

23 NOV 2020

Collection time (00:00-23:59)

10:39 (24 HR)

Collection date and time (derived)

23 NOV 2020 10:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Collection date (dd MMM yyyy)			23 NOV 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:20	23 NOV 2020 11:20
Nasopharyngeal Swab 2	No		

US3022103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

98.4 °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

23 NOV 2020 12:33

PC Open Date & Time

23 NOV 2020 12:24

PC Close Date & Time

23 NOV 2020 14:54

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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 98.1 °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	23 NOV 2020 17:46
PC Open Date & Time	23 NOV 2020 15:49
PC Close Date & Time	24 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

99.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

24 NOV 2020 12:30

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

25 NOV 2020 15:52

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

97.6 °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

27 NOV 2020 08:12

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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

28 NOV 2020 11:30

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

97.4 °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

29 NOV 2020 00:24

PC Open Date & Time

28 NOV 2020 12:00

PC Close Date & Time

29 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 NOV 2020 16:01

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 NOV 2020 12:34

PC Open Date & Time

23 NOV 2020 12:24

PC Close Date & Time

23 NOV 2020 14:54

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

23 NOV 2020 17:47

PC Open Date & Time

23 NOV 2020 15:49

PC Close Date & Time

24 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

24 NOV 2020 12:31

PC Open Date & Time

24 NOV 2020 12:00

PC Close Date & Time

25 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

25 NOV 2020 15:52

PC Open Date & Time

25 NOV 2020 12:00

PC Close Date & Time

26 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

27 NOV 2020 08:12

PC Open Date & Time

26 NOV 2020 12:00

PC Close Date & Time

27 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

28 NOV 2020 11:30

PC Open Date & Time

27 NOV 2020 12:00

PC Close Date & Time

28 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

29 NOV 2020 00:24

PC Open Date & Time

28 NOV 2020 12:00

PC Close Date & Time

29 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

29 NOV 2020 16:01

PC Open Date & Time

29 NOV 2020 12:00

PC Close Date & Time

30 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

No ☒

Yes ☐

PC Time stamp	23 NOV 2020 12:34
PC Open Date & Time	23 NOV 2020 12:24
PC Close Date & Time	23 NOV 2020 14:54

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

No ☒

Yes ☐

PC Time stamp	23 NOV 2020 17:48
PC Open Date & Time	23 NOV 2020 15:49
PC Close Date & Time	24 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

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 ☒

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

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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US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	25 NOV 2020 15:53
PC Open Date & Time	25 NOV 2020 12:00
PC Close Date & Time	26 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

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)

95 of 2061

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	27 NOV 2020 08:13
PC Open Date & Time	26 NOV 2020 12:00
PC Close Date & Time	27 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

97 of 2061

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	28 NOV 2020 11:30
PC Open Date & Time	27 NOV 2020 12:00
PC Close Date & Time	28 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

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 ☒

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	29 NOV 2020 00:25
PC Open Date & Time	28 NOV 2020 12:00
PC Close Date & Time	29 NOV 2020 11:59

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

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 ☒

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

Yes <input type="checkbox"/>	
PC Time stamp	29 NOV 2020 16:01
PC Open Date & Time	29 NOV 2020 12:00
PC Close Date & Time	30 NOV 2020 11:59

US3022103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022103

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

14 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022103

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 DEC 2020
Time of assessment (00:00-23:59)	10:52 (24 HR)
Vital Signs Date and Time (derived)	21 DEC 2020 10:52
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 DEC 2020

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

US3022103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 DEC 2020
Collection time (00:00-23:59)	11:19 (24 HR)
Collection date and time (derived)	21 DEC 2020 11:19

US3022103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:32

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	01 OCT 2020 14:28:43
Patient Cloud Open Date & Time	30 SEP 2020 00:01
Patient Cloud Close Date & Time	04 OCT 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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"/>

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 OCT 2020 11:43:13

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 OCT 2020 18:56:20
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:04:03

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☒

Yes ☐

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

11 NOV 2020 00:01:41

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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°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"/>

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 NOV 2020 22:18:08

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 NOV 2020 00:25:37

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 DEC 2020 00:02:00
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

13 DEC 2020 00:01:38

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

22 DEC 2020 12:07:00

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

27 DEC 2020 11:39:09

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 JAN 2021 01:01:15

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 09:00:50

Patient Cloud Open Date & Time

10 JAN 2021 00:01

Patient Cloud Close Date & Time

14 JAN 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

17 JAN 2021 00:52:20

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	26 JAN 2021 18:00:41
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 JAN 2021 00:01:35

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 FEB 2021 18:02:52

Patient Cloud Open Date & Time

07 FEB 2021 00:01

Patient Cloud Close Date & Time

11 FEB 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 12:00:16

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

25 FEB 2021 07:23:55

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 MAR 2021 17:00:49

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 MAR 2021 19:05:10

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

14 MAR 2021 01:04:29

Patient Cloud Open Date & Time

14 MAR 2021 00:01

Patient Cloud Close Date & Time

18 MAR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

21 MAR 2021 00:02:47

Patient Cloud Open Date & Time

21 MAR 2021 00:01

Patient Cloud Close Date & Time

25 MAR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

28 MAR 2021 01:33:33

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

04 APR 2021 00:03:07

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 13:22:14

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 00:15:51

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

25 APR 2021 00:02:22

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 17:22:33

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

16 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 299

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

23 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 306

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 MAY 2021 00:01
Patient Cloud Close Date & Time	03 JUN 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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="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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

27 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	04 JUL 2021 00:01
Patient Cloud Close Date & Time	08 JUL 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUL 2021 00:01
Patient Cloud Close Date & Time	15 JUL 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 JUL 2021 00:01
Patient Cloud Close Date & Time	29 JUL 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

08 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 AUG 2021 00:01
Patient Cloud Close Date & Time	19 AUG 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

12 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

16 SEP 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

19 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

23 SEP 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 SEP 2021 00:01
Patient Cloud Close Date & Time	30 SEP 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

Patient Cloud Open Date & Time	03 OCT 2021 00:01
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Patient Cloud Close Date & Time	07 OCT 2021 23:59
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US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 439

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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="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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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="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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 OCT 2021 00:01
Patient Cloud Close Date & Time	04 NOV 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 481

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 NOV 2021 00:01
Patient Cloud Close Date & Time	25 NOV 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	05 DEC 2021 00:01
Patient Cloud Close Date & Time	09 DEC 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

09 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 544

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 FEB 2022 00:01
Patient Cloud Close Date & Time	17 FEB 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

20 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 MAR 2022 00:01
Patient Cloud Close Date & Time	24 MAR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐
Yes ☐

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 APR 2022 00:01
Patient Cloud Close Date & Time	07 APR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐
Yes ☐

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 649

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

08 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

22 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐
Yes ☐

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

29 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	26 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2022 00:01
Patient Cloud Close Date & Time	07 JUL 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUL 2022 00:01
Patient Cloud Close Date & Time	14 JUL 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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="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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 726

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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="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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

07 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Close Date & Time](#)

18 AUG 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 754

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

21 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐
Yes ☐

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

04 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

DAY 782

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

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

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

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

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

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

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

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

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 SEP 2022 00:01
Patient Cloud Close Date & Time	22 SEP 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2022 23:59

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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="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"/>

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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

[Patient Cloud Open Date & Time](#)

02 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2022 23:59

US3022103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:53:37

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		02 MAR 2021 17:01:03

US3022103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:14:41

Generated On: 09 Jun 2021 14:53:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

30 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022103

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022103

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 16:55:31

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 13 Apr 2021 22:14:41

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 13 Apr 2021 22:14:41

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 11:16:20

Generated On: 09 Jun 2021 14:53:37

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022103

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:16:20

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022103

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

Was this visit performed? Yes ☐
No ☐

Visit date (dd MMM yyyy) _____

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID _____

US3022103

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

Was the physical examination performed?

Yes ☐

No ☐

Date of examination (dd MMM yyyy)

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

US3022103

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

Was the sample collected?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>
Collection date (<i>dd MMM yyyy</i>)	<hr/>
Collection time (<i>00:00-23:59</i>)	<hr/>
Collection date and time (derived)	<hr/>

US3022103

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022103

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:53:37

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3022103

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

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 16:55:30

Generated On: 09 Jun 2021 14:53:37

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

Visit date (dd MMM yyyy)	12 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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US3022103

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

Form: Unblinding

Data signed: (b) (4) 13 Apr 2021 22:14:41

Generated On: 09 Jun 2021 14:53:37

Date of updated informed consent (dd MMM yyyy) 12 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 12 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3022103

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 16:55:30

Generated On: 09 Jun 2021 14:53:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	09:36 (24 HR)
Collection date and time (derived)	12 JAN 2021 09:36

US3022103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 23 Feb 2021 16:55:30

Generated On: 09 Jun 2021 14:53:37

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	09:44
Collection Date and Time (derived)	12 JAN 2021 09:44

US3022103

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 16:55:30

Generated On: 09 Jun 2021 14:53:37

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

AEID

Adverse event

NECK PAIN

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

14 AUG 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

17 AUG 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

PRODUCTION RELEASE (v12.003

316 of 2061

EAB) (1725)

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

AEID	
Adverse event	ELEVATED LIVER ENZYMES
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)	17 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

AEID	USA-US051-2020-MRNA-1273-P30 1000004
Adverse event	INTERMITTENT EPIGASTRIC PAIN
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)	16 AUG 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 type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	17 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

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 checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	PENDING MEDICAL RECORDS.
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 16:55:30

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

Name of Medication FLUTICASONE

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input checked="" 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 2003	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
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"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

Name of Medication KETOCONAZOLE

Prophylaxis Yes ☐
No ☒

Indication ONYCHOMYCOSIS BILATERAL

Dose per administration 200-400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

	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 2018	
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"/>

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

Name of Medication SUCRALFATE

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC PAIN

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 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 (4)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication EPIGASTRIC PAIN

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 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 (5)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication NECK PAIN

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	16 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 NOV 2020		
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 16:55:30

Generated On: 09 Jun 2021 14:53:37

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 16:55:30

Generated On: 09 Jun 2021 14:53:37

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
15 SEP 2020	MRI OF THE ABDOMEN	Adverse Event	
16 AUG 2020	CT ABDOMEN PELVIS WITH CONTRAST	Adverse Event	

US3022103

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:53:37

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

US3022103

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:53:37

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 ☐

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	15/SEP/2020 10:48
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	05/OCT/2020 08:54
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	23/OCT/2020 20:35
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	10/NOV/2020 17:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	24/NOV/2020 07:38
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	01/DEC/2020 16:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	09/DEC/2020 21:19
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	16/DEC/2020 16:12
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	02/MAR/2021 09:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	09/MAR/2021 12:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	15/MAR/2021 11:21
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Data signed: (b) (4) 25 Mar 2021 23:03:03

Generated On: 09 Jun 2021 14:53:37

SAEID	USA-US051-2020-MRNA-1273-P301000004
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	12
Date of submission (Pre-filled from custom function)	17/MAR/2021 09:45
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022103 (Prod: Meridian Clinical Research-Savannah)

US3022103

Form: Participant Creation

Generated On: 09 Jun 2021 14:53:37

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:54:59
User entered 'US3022103'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Jul 2020 18:49:18

US3022103

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:25:56

US3022103

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Jul 2020 18:49:19

US3022103

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Clinic (Clinic)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:25:56

US3022103

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'SCRN'	(b) (4), (b) (6) System	31 Jul 2020 20:25:56

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered (b) (6) 1960'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Jul 2020 18:49:19

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '59'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'YEARS'	(b) (4), (b) (6) System	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered '59'	(b) (4), (b) (6) System	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Female (F)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'I'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:53:37

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:15

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'Jul 2020'	(b) (4), (b) (6) System	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered '2020'	(b) (4), (b) (6) System	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Amendment 1 (1)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:35

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Jul 2020 18:49:19

US3022103

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:53:37

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'I'	(b) (4), (b) (6) System	31 Jul 2020 20:26:41

US3022103

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:26:41

US3022103

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:53:37

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:13

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	31 Jul 2020 21:07:15
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Jul 2020 21:07:15
Data point term sent to Coder	System	31 Jul 2020 21:05:57
User entered 'seasonal allergies'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'un UNK 2003'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'Jan 2003'	(b) (4), (b) (6) System	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered '2003'	(b) (4), (b) (6) System	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered empty.	(b) (4), (b) (6) System	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered empty.	(b) (4), (b) (6) System	31 Jul 2020 21:05:29

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral EAR. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 09:48:27
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Onychomycosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 14:08:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 14:08:48
Data point term sent to Coder	System	31 Aug 2020 13:16:57
Query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral EAR. Update Med History eCRF as appropriate. ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:16:26
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:16:18
User entered 'bilateral onychomycosis' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:16:18
User opened query 'Per DM CLR: Please review and reflect if this involves the Left, Right or Bilateral EAR. Update Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	28 Aug 2020 09:16:01
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Ear infection fungal, LLT: Ear infection fungal - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:04:11
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	03 Aug 2020 17:04:11
Data point term sent to Coder	System	31 Jul 2020 21:05:58
User entered 'otomycosis'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'un UNK 2018'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'Jan 2018'	(b) (4), (b) (6) System	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered '2018'	(b) (4), (b) (6) System	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered empty.	(b) (4), (b) (6) System	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered empty.	(b) (4), (b) (6) System	31 Jul 2020 21:05:54

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:08:54
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:08:54
Data point term sent to Coder	System	31 Aug 2020 13:07:35
User entered 'post menopausal'	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'un UNK 2010'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'Jan 2010'	(b) (4), (b) (6) System	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered '2010'	(b) (4), (b) (6) System	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered empty.	(b) (4), (b) (6) System	31 Aug 2020 13:06:58

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '15:05'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered '31 Jul 2020 15:05'	(b) (4), (b) (6) System	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '163.5' cm	(b) (4) Stella Yoon (b) (4)	31 Jul 2020 21:06:32
DataPoint set to visible.	(b) (4) System	31 Jul 2020 20:26:41

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '63.9' kg	(b) (4) Stella Yoon (b) (4)	31 Jul 2020 21:06:32
DataPoint set to visible.	(b) (4) System	31 Jul 2020 20:26:41

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
Amendment Manager: User entered '23.90371'	(b) (4), (b) (6) System	16 Sep 2020 23:39:55
User entered '23.9'	System	31 Jul 2020 21:06:32
DataPoint set to visible.	System	31 Jul 2020 20:26:41

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'kg/m2'	(b) (4), (b) (6) System	31 Jul 2020 21:06:32
DataPoint set to visible.	System	31 Jul 2020 20:26:41

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
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) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 02:01:01
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 16:51:49
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:51:38
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) (b) (4), (b) (6)	22 Oct 2020 09:35:26
User entered '98.5' F	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:51:38
User entered 'Oral (Oral)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:51:38
User entered '72'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'bpm'	(b) (4), (b) (6) System	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:51:38
User entered '14'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'breaths/min'	(b) (4), (b) (6) System	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:51:38
User entered '100'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'mmHg'	(b) (4), (b) (6) System	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:51:38
User entered '70'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User entered 'mmHg'	(b) (4), (b) (6) System	31 Jul 2020 21:06:32

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	(b) (4), (b) (6) 26 Apr 2021 13:12:40

US3022103

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	(b) (4), (b) (6) 26 Apr 2021 13:12:40

US3022103

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:40

US3022103

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:40

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:37

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
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) (b) (4), (b) (6)	01 Sep 2020 09:31:30
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).	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 13:07:16
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 12:27:03
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:37

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:37

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'un UNK 2010'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 14:53:37

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:06:55

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

[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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

[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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

[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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'I'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'I'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:53:37

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:12:40
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Lives in community with ongoing person to person transmission'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:25

US3022103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:36

US3022103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:36

US3022103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Clinic (Clinic)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:36

US3022103

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'VISIT1'	(b) (4), (b) (6) System	31 Jul 2020 21:07:36

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Jul 2020 20:14:15

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:37

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:32:32
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:32:32
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 20:14:15
User entered '100470' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Jul 2020 20:14:15

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:37

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	31 Jul 2020 20:14:15

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:37

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:37

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

US3022103

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:53:37

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:07:50

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 02:01:17
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 16:47:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:47:33
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) (b) (4), (b) (6)	23 Oct 2020 08:57:20
User entered '163.5' cm	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:47:33
User entered '63.9' kg	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 02:01:17
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 16:47:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:47:33
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) (b) (4), (b) (6)	23 Oct 2020 08:57:20
User entered '163.5' cm	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:47:33
User entered '63.9' kg	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '15:05'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered '31 Jul 2020 15:05'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '98.5' F	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Oral (Oral)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '72'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'bpm'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '14'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'breaths/min'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '100'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'mmHg'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '70'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'mmHg'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:37

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 02:01:17
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 16:47:43
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:47:33
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) (b) (4), (b) (6)	23 Oct 2020 08:57:20
User entered '163.5' cm	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:53:37

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	03 Nov 2020 16:47:33
User entered '63.9' kg	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
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) (4), (b) (6) (b) (4), (b) (6)	05 Aug 2020 16:41:28
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'per protocol, 30 minutes post dose' (Site from System).	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:19
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).		31 Jul 2020 21:09:11
User entered '16:56'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered '31 Jul 2020 16:56'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '36.7' C	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Oral (Oral)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '72'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'bpm'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '14'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'breaths/min'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '108'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'mmHg'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '70'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'mmHg'	(b) (4), (b) (6) System	31 Jul 2020 21:09:11

US3022103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:27

US3022103

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:27

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '16:20'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered '31 Jul 2020 16:20'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Left Arm (LEFT ARM)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'ONCE'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:47

US3022103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:47

US3022103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '16:02'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:47

US3022103

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered '31 Jul 2020 16:02'	(b) (4), (b) (6) System	31 Jul 2020 21:09:47

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:53:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '31 Jul 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '15:35'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered '31 Jul 2020 15:35'	(b) (4), (b) (6) System	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered empty.	(b) (4), (b) (6) System	31 Jul 2020 21:09:57

US3022103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:10:01

US3022103

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'I'	(b) (4), (b) (6) System	31 Jul 2020 21:10:01

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:53:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '0984129c-cd0b-4de6-87a0-37598747686b' User entered 'Yes (Y)'	System	31 Jul 2020 20:53:59
	System	31 Jul 2020 20:53:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:53:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '0984129c-cd0b-4de6-87a0-37598747686b' User entered '98.1'	System	31 Jul 2020 20:53:59
	System	31 Jul 2020 20:53:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:53:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '0984129c-cd0b-4de6-87a0-37598747686b' User entered 'No (N)'	System	31 Jul 2020 20:53:59
	System	31 Jul 2020 20:53:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:53:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '0984129c-cd0b-4de6-87a0-37598747686b' User entered '31 Jul 2020 16:53'	System	31 Jul 2020 20:53:59
	System	31 Jul 2020 20:53:59

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 16:40'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 19:10'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:23', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d7bbffb-ad23-4472-85a5-b5df512c66ed' User entered 'Yes (Y)'	System	01 Aug 2020 00:13:39
	System	01 Aug 2020 00:13:39

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:30', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d7bbffb-ad23-4472-85a5-b5df512c66ed' User entered '97.7'	System	01 Aug 2020 00:13:39
	System	01 Aug 2020 00:13:39

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:33', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d7bbffb-ad23-4472-85a5-b5df512c66ed' User entered 'No (N)'	System	01 Aug 2020 00:13:39
	System	01 Aug 2020 00:13:39

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d7bbffb-ad23-4472-85a5-b5df512c66ed' User entered '31 Jul 2020 20:13'	System	01 Aug 2020 00:13:39
	System	01 Aug 2020 00:13:39

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 20:05'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 2'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

Was TEMPERATURE taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:26:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'da81f6a1-157c-4669-bfd6-2ec3c41fe2a1' User entered 'Yes (Y)'	System	01 Aug 2020 22:28:41
	System	01 Aug 2020 22:28:41

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:30', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'da81f6a1-157c-4669-bfd6-2ec3c41fe2a1' User entered '99.2'	System	01 Aug 2020 22:28:41
	System	01 Aug 2020 22:28:41

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'da81f6a1-157c-4669-bfd6-2ec3c41fe2a1' User entered 'No (N)'	System	01 Aug 2020 22:28:41
	System	01 Aug 2020 22:28:41

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'da81f6a1-157c-4669-bfd6-2ec3c41fe2a1' User entered '01 Aug 2020 18:28'	System	01 Aug 2020 22:28:41
	System	01 Aug 2020 22:28:41

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 3'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:12:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ace41f4d-6675-457f-99d7-487fcb62cffe' User entered 'Yes (Y)'	System	02 Aug 2020 23:14:54
	System	02 Aug 2020 23:14:54

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:13:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ace41f4d-6675-457f-99d7-487fcb62cffc' User entered '99.1'	System	02 Aug 2020 23:14:54
	System	02 Aug 2020 23:14:54

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:14:42', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ace41f4d-6675-457f-99d7-487fcb62cffe'	System	02 Aug 2020 23:14:54
User entered 'No (N)'	System	02 Aug 2020 23:14:54

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:14:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ace41f4d-6675-457f-99d7-487fcb62cffe'	System	02 Aug 2020 23:14:54
User entered '02 Aug 2020 19:14'	System	02 Aug 2020 23:14:54

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '03 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 4'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:39:44', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6f642f53-8580-4f71-a4e1-036e2efbe059' User entered 'Yes (Y)'	System	04 Aug 2020 01:40:00
	System	04 Aug 2020 01:40:00

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:39:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6f642f53-8580-4f71-a4e1-036e2efbe059' User entered '97.4'	System	04 Aug 2020 01:40:00
	System	04 Aug 2020 01:40:00

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:39:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6f642f53-8580-4f71-a4e1-036e2efbe059'	System	04 Aug 2020 01:40:00
User entered 'No (N)'	System	04 Aug 2020 01:40:00

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:39:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6f642f53-8580-4f71-a4e1-036e2efbe059'	System	04 Aug 2020 01:40:00
User entered '03 Aug 2020 21:39'	System	04 Aug 2020 01:40:00

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '04 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 5'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:13:48', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1a690d61-2750-4fb3-8611-2c87f554858c' User entered 'Yes (Y)'	System	05 Aug 2020 01:15:05
	System	05 Aug 2020 01:15:05

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:14:57', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1a690d61-2750-4fb3-8611-2c87f554858c' User entered '98.0'	System	05 Aug 2020 01:15:05
	System	05 Aug 2020 01:15:05

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:14:31', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1a690d61-2750-4fb3-8611-2c87f554858c' User entered 'No (N)'	System	05 Aug 2020 01:15:05
	System	05 Aug 2020 01:15:05

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1a690d61-2750-4fb3-8611-2c87f554858c' User entered '04 Aug 2020 21:15'	System	05 Aug 2020 01:15:05
	System	05 Aug 2020 01:15:05

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '05 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 6'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d84d157-323a-4568-9bf3-aa8f84a25cbd' User entered 'Yes (Y)'	System	05 Aug 2020 22:57:55
	System	05 Aug 2020 22:57:55

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d84d157-323a-4568-9bf3-aa8f84a25cbd' User entered '97.9'	System	05 Aug 2020 22:57:55
	System	05 Aug 2020 22:57:55

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:51', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d84d157-323a-4568-9bf3-aa8f84a25cbd'	System	05 Aug 2020 22:57:55
User entered 'No (N)'	System	05 Aug 2020 22:57:55

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:54', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d84d157-323a-4568-9bf3-aa8f84a25cbd' User entered '05 Aug 2020 18:57'	System	05 Aug 2020 22:57:55
	System	05 Aug 2020 22:57:55

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '05 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '06 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 7'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T18:58:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b2058aa4-27dd-4601-a937-8fa47bef6f12'	System	06 Aug 2020 23:00:06
User entered 'Yes (Y)'	System	06 Aug 2020 23:00:06

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T18:59:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b2058aa4-27dd-4601-a937-8fa47bef6f12'	System	06 Aug 2020 23:00:06
User entered '96.9'	System	06 Aug 2020 23:00:06

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T18:59:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b2058aa4-27dd-4601-a937-8fa47bef6f12'	System	06 Aug 2020 23:00:06
User entered 'No (N)'	System	06 Aug 2020 23:00:06

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b2058aa4-27dd-4601-a937-8fa47bef6f12'	System	06 Aug 2020 23:00:06
User entered '06 Aug 2020 19:00'	System	06 Aug 2020 23:00:06

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '06 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:05', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d' User entered 'None (1)'	System	31 Jul 2020 20:54:53
	System	31 Jul 2020 20:54:53

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d' User entered 'No (N)'	System	31 Jul 2020 20:54:53
	System	31 Jul 2020 20:54:53

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d' User entered 'No (N)'	System	31 Jul 2020 20:54:53
	System	31 Jul 2020 20:54:53

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:44', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d' User entered 'None (1)'	System	31 Jul 2020 20:54:53
	System	31 Jul 2020 20:54:53

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:51', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '03e56a68-2bc0-4f72-b957-03512db54c3d' User entered '31 Jul 2020 16:54'	System	31 Jul 2020 20:54:53
	System	31 Jul 2020 20:54:53

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 16:40'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 19:10'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:42', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb' User entered 'None (1)'	System	01 Aug 2020 00:13:57
	System	01 Aug 2020 00:13:57

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:45', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb' User entered 'No (N)'	System	01 Aug 2020 00:13:57
	System	01 Aug 2020 00:13:57

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb' User entered 'No (N)'	System	01 Aug 2020 00:13:57
	System	01 Aug 2020 00:13:57

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb' User entered 'None (1)'	System	01 Aug 2020 00:13:57
	System	01 Aug 2020 00:13:57

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:13:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc75405e-b34b-4941-9bf8-6a43f0ec8eeb' User entered '31 Jul 2020 20:13'	System	01 Aug 2020 00:13:57
	System	01 Aug 2020 00:13:57

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 20:05'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 2'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9'	System	01 Aug 2020 22:30:04
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 22:30:04

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:28:54', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9' User entered 'No (N)'	System	01 Aug 2020 22:30:04
	System	01 Aug 2020 22:30:04

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:29:45', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9' User entered 'No (N)'	System	01 Aug 2020 22:30:04
	System	01 Aug 2020 22:30:04

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:29:55', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9' User entered 'None (1)'	System	01 Aug 2020 22:30:04
	System	01 Aug 2020 22:30:04

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5a95a813-4a3f-41e1-ad45-e9ba179064e9' User entered '01 Aug 2020 18:30'	System	01 Aug 2020 22:30:04
	System	01 Aug 2020 22:30:04

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 3'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:15', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df' User entered 'None (1)'	System	02 Aug 2020 23:15:29
	System	02 Aug 2020 23:15:29

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:18', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df' User entered 'No (N)'	System	02 Aug 2020 23:15:29
	System	02 Aug 2020 23:15:29

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:21', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df' User entered 'No (N)'	System	02 Aug 2020 23:15:29
	System	02 Aug 2020 23:15:29

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df' User entered 'None (1)'	System	02 Aug 2020 23:15:29
	System	02 Aug 2020 23:15:29

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '21153255-9ace-4b4f-b7e2-58822ea483df' User entered '02 Aug 2020 19:15'	System	02 Aug 2020 23:15:29
	System	02 Aug 2020 23:15:29

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '03 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 4'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a' User entered 'None (1)'	System	04 Aug 2020 01:40:15
	System	04 Aug 2020 01:40:15

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a' User entered 'No (N)'	System	04 Aug 2020 01:40:15
	System	04 Aug 2020 01:40:15

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:07', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a' User entered 'No (N)'	System	04 Aug 2020 01:40:15
	System	04 Aug 2020 01:40:15

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a' User entered 'None (1)'	System	04 Aug 2020 01:40:15
	System	04 Aug 2020 01:40:15

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c1eda4c6-9b82-466d-a8ef-5d41a6bfe13a' User entered '03 Aug 2020 21:40'	System	04 Aug 2020 01:40:15
	System	04 Aug 2020 01:40:15

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '04 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 5'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051' User entered 'None (1)'	System	05 Aug 2020 01:15:16
	System	05 Aug 2020 01:15:16

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051' User entered 'No (N)'	System	05 Aug 2020 01:15:16
	System	05 Aug 2020 01:15:16

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051' User entered 'No (N)'	System	05 Aug 2020 01:15:16
	System	05 Aug 2020 01:15:16

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:11', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051' User entered 'None (1)'	System	05 Aug 2020 01:15:16
	System	05 Aug 2020 01:15:16

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'bc217a52-ad4a-4cc9-90f3-3f58caa2c051' User entered '04 Aug 2020 21:15'	System	05 Aug 2020 01:15:16
	System	05 Aug 2020 01:15:16

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '05 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 6'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:57:58', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307' User entered 'None (1)'	System	05 Aug 2020 22:58:17
	System	05 Aug 2020 22:58:17

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307' User entered 'No (N)'	System	05 Aug 2020 22:58:17
	System	05 Aug 2020 22:58:17

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:02', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307' User entered 'No (N)'	System	05 Aug 2020 22:58:17
	System	05 Aug 2020 22:58:17

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307' User entered 'None (1)'	System	05 Aug 2020 22:58:17
	System	05 Aug 2020 22:58:17

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b6fb2f63-09e5-4566-91a9-9158c3439307' User entered '05 Aug 2020 18:58'	System	05 Aug 2020 22:58:17
	System	05 Aug 2020 22:58:17

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '05 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '06 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 7'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58'	System	06 Aug 2020 23:00:22
User entered 'None (1)'	System	06 Aug 2020 23:00:22

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58' User entered 'No (N)'	System	06 Aug 2020 23:00:22
	System	06 Aug 2020 23:00:22

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58' User entered 'No (N)'	System	06 Aug 2020 23:00:22
	System	06 Aug 2020 23:00:22

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:19', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58'	System	06 Aug 2020 23:00:22
User entered 'None (1)'	System	06 Aug 2020 23:00:22

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:21', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '14b29f1f-357f-4bcf-8d3f-6f7341d18c58' User entered '06 Aug 2020 19:00'	System	06 Aug 2020 23:00:22
	System	06 Aug 2020 23:00:22

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '06 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47' User entered 'None (0)'	System	31 Jul 2020 20:55:18
	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:54:59', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47' User entered 'None (0)'	System	31 Jul 2020 20:55:18
	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47' User entered 'None (0)'	System	31 Jul 2020 20:55:18
	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:05', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47' User entered 'None (0)'	System	31 Jul 2020 20:55:18
	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:07', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47' User entered 'None (0)'	System	31 Jul 2020 20:55:18
	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47' User entered 'None (0)'	System	31 Jul 2020 20:55:18
	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47' User entered 'No (N)'	System	31 Jul 2020 20:55:18
	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T16:55:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4d3cc26-f5bf-4c08-a9ef-be1afb7b7d47' User entered '31 Jul 2020 16:55'	System	31 Jul 2020 20:55:18
	System	31 Jul 2020 20:55:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 16:40'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 19:10'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered 'None (0)'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered 'None (0)'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered 'None (0)'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered 'None (0)'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered 'None (0)'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered 'None (0)'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:19', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered 'No (N)'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-07-31T20:14:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a63c356b-4c6f-4a35-b963-d4dd5ca6d0ca' User entered '31 Jul 2020 20:14'	System	01 Aug 2020 00:14:28
	System	01 Aug 2020 00:14:28

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '31 Jul 2020 20:05'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '01 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 2'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1' User entered 'No interference with activity (1)'	System	01 Aug 2020 22:31:35
	System	01 Aug 2020 22:31:35

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1' User entered 'Some interference with activity (2)'	System	01 Aug 2020 22:31:35
	System	01 Aug 2020 22:31:35

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:48', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1' User entered 'None (0)'	System	01 Aug 2020 22:31:35
	System	01 Aug 2020 22:31:35

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:30:58', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1' User entered 'None (0)'	System	01 Aug 2020 22:31:35
	System	01 Aug 2020 22:31:35

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:31:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1' User entered 'None (0)'	System	01 Aug 2020 22:31:35
	System	01 Aug 2020 22:31:35

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:31:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1' User entered 'No interference with activity (1)'	System	01 Aug 2020 22:31:35
	System	01 Aug 2020 22:31:35

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:31:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1' User entered 'No (N)'	System	01 Aug 2020 22:31:35
	System	01 Aug 2020 22:31:35

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-01T18:31:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '27920f58-c877-4419-85e3-f36ab7c66ec1' User entered '01 Aug 2020 18:31'	System	01 Aug 2020 22:31:35
	System	01 Aug 2020 22:31:35

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '01 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '02 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 3'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5' User entered 'None (0)'	System	02 Aug 2020 23:15:59
	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5' User entered 'None (0)'	System	02 Aug 2020 23:15:59
	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5' User entered 'None (0)'	System	02 Aug 2020 23:15:59
	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:45', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5' User entered 'None (0)'	System	02 Aug 2020 23:15:59
	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:47', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5' User entered 'None (0)'	System	02 Aug 2020 23:15:59
	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5' User entered 'None (0)'	System	02 Aug 2020 23:15:59
	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5' User entered 'No (N)'	System	02 Aug 2020 23:15:59
	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-02T19:15:57', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '79b4b9be-3ff7-49a4-ac0a-c07c0dc59ac5' User entered '02 Aug 2020 19:15'	System	02 Aug 2020 23:15:59
	System	02 Aug 2020 23:15:59

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '02 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '03 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 4'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41' User entered 'None (0)'	System	04 Aug 2020 01:40:47
	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:22', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'No interference with activity (1)'	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41' User entered 'None (0)'	System	04 Aug 2020 01:40:47
	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'No interference with activity (1)'	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41' User entered 'None (0)'	System	04 Aug 2020 01:40:47
	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41' User entered 'None (0)'	System	04 Aug 2020 01:40:47
	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41'	System	04 Aug 2020 01:40:47
User entered 'No (N)'	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-03T21:40:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '514560f4-fd2f-4e5d-b4fe-fc3d87cbfd41' User entered '03 Aug 2020 21:40'	System	04 Aug 2020 01:40:47
	System	04 Aug 2020 01:40:47

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '03 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '04 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 5'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:17', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5' User entered 'None (0)'	System	05 Aug 2020 01:15:39
	System	05 Aug 2020 01:15:39

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:20', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5' User entered 'None (0)'	System	05 Aug 2020 01:15:39
	System	05 Aug 2020 01:15:39

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:22', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5' User entered 'None (0)'	System	05 Aug 2020 01:15:39
	System	05 Aug 2020 01:15:39

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5' User entered 'None (0)'	System	05 Aug 2020 01:15:39
	System	05 Aug 2020 01:15:39

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5' User entered 'None (0)'	System	05 Aug 2020 01:15:39
	System	05 Aug 2020 01:15:39

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5' User entered 'None (0)'	System	05 Aug 2020 01:15:39
	System	05 Aug 2020 01:15:39

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5' User entered 'No (N)'	System	05 Aug 2020 01:15:39
	System	05 Aug 2020 01:15:39

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-04T21:15:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2188b074-2bce-42b0-8963-9e8f245269e5' User entered '04 Aug 2020 21:15'	System	05 Aug 2020 01:15:39
	System	05 Aug 2020 01:15:39

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '04 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '05 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 6'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2' User entered 'None (0)'	System	05 Aug 2020 22:58:43
	System	05 Aug 2020 22:58:43

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:26', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2' User entered 'None (0)'	System	05 Aug 2020 22:58:43
	System	05 Aug 2020 22:58:43

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:28', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2' User entered 'None (0)'	System	05 Aug 2020 22:58:43
	System	05 Aug 2020 22:58:43

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2' User entered 'None (0)'	System	05 Aug 2020 22:58:43
	System	05 Aug 2020 22:58:43

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:31', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2' User entered 'None (0)'	System	05 Aug 2020 22:58:43
	System	05 Aug 2020 22:58:43

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:33', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2' User entered 'None (0)'	System	05 Aug 2020 22:58:43
	System	05 Aug 2020 22:58:43

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2'	System	05 Aug 2020 22:58:43
User entered 'No (N)'	System	05 Aug 2020 22:58:43

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-05T18:58:39', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '58e93a88-81fa-4b8b-ae89-427f12ac67a2' User entered '05 Aug 2020 18:58'	System	05 Aug 2020 22:58:43
	System	05 Aug 2020 22:58:43

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '05 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '06 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	31 Jul 2020 20:27:08
User entered 'Day 7'	System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered 'None (0)'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:00:39', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered 'None (0)'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered 'None (0)'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:02', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered 'None (0)'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered 'None (0)'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered 'None (0)'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered 'No (N)'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-08-06T19:01:15', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c36d4b01-9fbe-4041-9721-a98b52f12b9f' User entered '06 Aug 2020 19:01'	System	06 Aug 2020 23:01:18
	System	06 Aug 2020 23:01:18

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '06 Aug 2020 12:00'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '07 Aug 2020 11:59'	(b) (4), (b) (6) System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:31

US3022103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '10 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:31

US3022103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:31

US3022103

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:31

US3022103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	10 Aug 2020 20:33:35

US3022103

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'I'	(b) (4), (b) (6) System	10 Aug 2020 20:33:35

US3022103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:25

US3022103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '17 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:25

US3022103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:25

US3022103

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:25

US3022103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:52:29

US3022103

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 Apr 2021 07:56:01
User entered 'I'	(b) (4), (b) (6) System	17 Aug 2020 22:52:29

US3022103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:41:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:26

US3022103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:41:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '21 Aug 2020'	(b) (4) Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:26

US3022103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:41:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:26

US3022103

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:41:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Morgan Deal (b) (4)	12 Nov 2020 22:20:26
	(b) (4)	

US3022103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 06:41:35
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) Morgan Deal (b) (4) (b) (4)	12 Nov 2020 22:20:31

US3022103

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 29 Apr 2021 06:41:35
User entered 'I'	(b) (4), (b) (6) System	12 Nov 2020 22:20:31

US3022103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:43:14
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User closed query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 18:37:15
	(b) (4), (b) (6)	
Query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' answered with 'this is correct' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:43:21
	(b) (4), (b) (6)	
User opened query 'Visit 2 Date is < 25 days or > 35 days after Visit 1 vaccination. Please reconcile or confirm dates.' (Site from System).	System	02 Dec 2020 14:43:14
User entered '23 Nov 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:43:14
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[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 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:43:14
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'VISIT2'	(b) (4), (b) (6) System	02 Dec 2020 14:43:14

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User accepted default value 'Pre-Dose (PREDOSE)'		02 Dec 2020 14:47:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '23 Nov 2020'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '10:25'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered '23 Nov 2020 10:25'	(b) (4), (b) (6) System	02 Dec 2020 14:47:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '36.8' C	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '72'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'bpm'	(b) (4), (b) (6) System	02 Dec 2020 14:47:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '16'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'breaths/min'	(b) (4), (b) (6) System	02 Dec 2020 14:47:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '100'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'mmHg'	(b) (4), (b) (6) System	02 Dec 2020 14:47:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '64'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:39
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:53:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'mmHg'	(b) (4), (b) (6) System	02 Dec 2020 14:47:39

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	02 Dec 2020 14:49:18

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '23 Nov 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '12:34'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered '23 Nov 2020 12:34'	(b) (4), (b) (6) System	02 Dec 2020 14:49:18

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '36.9' C	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '67'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'bpm'	(b) (4), (b) (6) System	02 Dec 2020 14:49:18

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '16'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'breaths/min'	(b) (4), (b) (6) System	02 Dec 2020 14:49:18

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '116'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'mmHg'	(b) (4), (b) (6) System	02 Dec 2020 14:49:18

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '79'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:18
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:53:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'mmHg'	(b) (4), (b) (6) System	02 Dec 2020 14:49:18

US3022103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:52
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '23 Nov 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:47:52
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	23 Nov 2020 17:12:03
	(b) (4)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	23 Nov 2020 17:12:03
	(b) (4)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

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 14:01:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Chevon Roberts (b) (4)	23 Nov 2020 17:12:03
	(b) (4)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '23 Nov 2020'	Chevon Roberts (b) (6)	23 Nov 2020 17:12:03
	(b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '12:04'	Chevon Roberts (b) (4)	23 Nov 2020 17:12:03
	(b) (4)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered '23 Nov 2020 12:04'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Left Arm (LEFT ARM)'	Chevon Roberts (b) (4)	23 Nov 2020 17:12:03
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'ONCE'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:53:37

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:09

US3022103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '23 Nov 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:09
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '10:39'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:09
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered '23 Nov 2020 10:39'	(b) (4), (b) (6) System	02 Dec 2020 14:48:09

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:53:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '23 Nov 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:22
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	02 Dec 2020 14:48:22

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:22
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '11:20'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:22
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:53:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered '23 Nov 2020 11:20'	(b) (4), (b) (6) System	02 Dec 2020 14:48:22

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:37

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	02 Dec 2020 14:48:22

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:22
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:22
	(b) (4), (b) (6)	

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Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:53:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered empty.	(b) (4), (b) (6) System	02 Dec 2020 14:48:22

US3022103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:48:29
	(b) (4), (b) (6)	

US3022103

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'I'	(b) (4), (b) (6) System	02 Dec 2020 14:48:29

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9e2dc3b2-3603-4cd5-a128-534a7a133512' User entered 'Yes (Y)'	System	23 Nov 2020 17:33:43
	System	23 Nov 2020 17:33:43

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9e2dc3b2-3603-4cd5-a128-534a7a133512' User entered '98.4'	System	23 Nov 2020 17:33:43
	System	23 Nov 2020 17:33:43

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9e2dc3b2-3603-4cd5-a128-534a7a133512'	System	23 Nov 2020 17:33:43
User entered 'No (N)'	System	23 Nov 2020 17:33:43

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9e2dc3b2-3603-4cd5-a128-534a7a133512' User entered '23 Nov 2020 12:33'	System	23 Nov 2020 17:33:43
	System	23 Nov 2020 17:33:43

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 12:24'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 14:54'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b7efec8e-28d4-4728-8b85-3224c52f04c5' User entered 'Yes (Y)'	System	23 Nov 2020 22:46:44
	System	23 Nov 2020 22:46:44

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b7efec8e-28d4-4728-8b85-3224c52f04c5' User entered '98.1'	System	23 Nov 2020 22:46:44
	System	23 Nov 2020 22:46:44

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b7efec8e-28d4-4728-8b85-3224c52f04c5' User entered 'No (N)'	System	23 Nov 2020 22:46:44
	System	23 Nov 2020 22:46:44

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b7efec8e-28d4-4728-8b85-3224c52f04c5' User entered '23 Nov 2020 17:46'	System	23 Nov 2020 22:46:44
	System	23 Nov 2020 22:46:44

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 15:49'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '24 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 2'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:27:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c' User entered 'Yes (Y)'	System	24 Nov 2020 17:30:57
	System	24 Nov 2020 17:30:57

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c' User entered '99.2'	System	24 Nov 2020 17:30:57
	System	24 Nov 2020 17:30:57

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:33', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c' User entered 'Yes (Y)'	System	24 Nov 2020 17:30:57
	System	24 Nov 2020 17:30:57

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will updt' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	30 Nov 2020 04:44:51
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c'	(b) (4), (b) (6) (b) (4), (b) (6)	25 Nov 2020 17:00:12
User entered '1'	System	24 Nov 2020 17:30:57
	System	24 Nov 2020 17:30:57
	System	24 Nov 2020 17:30:57

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c' User entered '0'	System	24 Nov 2020 17:30:57
	System	24 Nov 2020 17:30:57

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:30:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2f913386-2b42-4b0b-8f3c-a4722ae8a08c' User entered '24 Nov 2020 12:30'	System	24 Nov 2020 17:30:57
	System	24 Nov 2020 17:30:57

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '24 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '25 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 3'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:50:07', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd43adff4-0012-43f0-a7c9-80144d0a044d' User entered 'Yes (Y)'	System	25 Nov 2020 20:52:12
	System	25 Nov 2020 20:52:12

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd43adff4-0012-43f0-a7c9-80144d0a044d' User entered '97.6'	System	25 Nov 2020 20:52:12
	System	25 Nov 2020 20:52:12

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:50:19', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd43adff4-0012-43f0-a7c9-80144d0a044d' User entered 'No (N)'	System	25 Nov 2020 20:52:12
	System	25 Nov 2020 20:52:12

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd43adff4-0012-43f0-a7c9-80144d0a044d' User entered '25 Nov 2020 15:52'	System	25 Nov 2020 20:52:12
	System	25 Nov 2020 20:52:12

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '25 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '26 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 4'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:21', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'f9fcbc17-51a3-49af-a558-32e0d8f9d4d5' User entered 'Yes (Y)'	System	27 Nov 2020 13:12:37
	System	27 Nov 2020 13:12:37

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'f9fcbc17-51a3-49af-a558-32e0d8f9d4d5' User entered '97.6'	System	27 Nov 2020 13:12:37
	System	27 Nov 2020 13:12:37

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:31', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'f9fcbb17-51a3-49af-a558-32e0d8f9d4d5' User entered 'No (N)'	System	27 Nov 2020 13:12:37
	System	27 Nov 2020 13:12:37

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'f9fcbc17-51a3-49af-a558-32e0d8f9d4d5' User entered '27 Nov 2020 08:12'	System	27 Nov 2020 13:12:37
	System	27 Nov 2020 13:12:37

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '26 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '27 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 5'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:29:55', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '18240082-7c02-4938-abd1-b9c07ddb8606' User entered 'Yes (Y)'	System	28 Nov 2020 16:30:10
	System	28 Nov 2020 16:30:10

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '18240082-7c02-4938-abd1-b9c07ddb8606' User entered '98.4'	System	28 Nov 2020 16:30:10
	System	28 Nov 2020 16:30:10

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '18240082-7c02-4938-abd1-b9c07ddb8606' User entered 'No (N)'	System	28 Nov 2020 16:30:10
	System	28 Nov 2020 16:30:10

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:05', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '18240082-7c02-4938-abd1-b9c07ddb8606' User entered '28 Nov 2020 11:30'	System	28 Nov 2020 16:30:10
	System	28 Nov 2020 16:30:10

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '27 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '28 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 6'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:23:45', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2fe06f8-3f42-442b-8639-546197cfee28' User entered 'Yes (Y)'	System	29 Nov 2020 05:24:25
	System	29 Nov 2020 05:24:25

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2fe06f8-3f42-442b-8639-546197cfee28' User entered '97.4'	System	29 Nov 2020 05:24:25
	System	29 Nov 2020 05:24:25

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2fe06f8-3f42-442b-8639-546197cfee28' User entered 'No (N)'	System	29 Nov 2020 05:24:25
	System	29 Nov 2020 05:24:25

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:22', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2fe06f8-3f42-442b-8639-546197cfee28' User entered '29 Nov 2020 00:24'	System	29 Nov 2020 05:24:25
	System	29 Nov 2020 05:24:25

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '28 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '29 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 7'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:00:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '644a8d75-25f3-4c85-b158-e81f9b4231a2' User entered 'Yes (Y)'	System	29 Nov 2020 21:01:12
	System	29 Nov 2020 21:01:12

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '644a8d75-25f3-4c85-b158-e81f9b4231a2' User entered '98.2'	System	29 Nov 2020 21:01:12
	System	29 Nov 2020 21:01:12

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '644a8d75-25f3-4c85-b158-e81f9b4231a2' User entered 'No (N)'	System	29 Nov 2020 21:01:12
	System	29 Nov 2020 21:01:12

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '644a8d75-25f3-4c85-b158-e81f9b4231a2' User entered '29 Nov 2020 16:01'	System	29 Nov 2020 21:01:12
	System	29 Nov 2020 21:01:12

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '29 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '30 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:33:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8' User entered 'None (1)'	System	23 Nov 2020 17:34:22
	System	23 Nov 2020 17:34:22

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8' User entered 'No (N)'	System	23 Nov 2020 17:34:22
	System	23 Nov 2020 17:34:22

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8' User entered 'No (N)'	System	23 Nov 2020 17:34:22
	System	23 Nov 2020 17:34:22

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8' User entered 'None (1)'	System	23 Nov 2020 17:34:22
	System	23 Nov 2020 17:34:22

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:19', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1111100d-6547-493b-9cb9-b4b595a35dd8' User entered '23 Nov 2020 12:34'	System	23 Nov 2020 17:34:22
	System	23 Nov 2020 17:34:22

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 12:24'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 14:54'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:48', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4' User entered 'Does not interfere with activity (2)'	System	23 Nov 2020 22:47:20
	System	23 Nov 2020 22:47:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:46:51', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4' User entered 'No (N)'	System	23 Nov 2020 22:47:20
	System	23 Nov 2020 22:47:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4' User entered 'No (N)'	System	23 Nov 2020 22:47:20
	System	23 Nov 2020 22:47:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4' User entered 'None (1)'	System	23 Nov 2020 22:47:20
	System	23 Nov 2020 22:47:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a4341e28-bd17-4b48-8217-fc0ccf1ae0b4' User entered '23 Nov 2020 17:47'	System	23 Nov 2020 22:47:20
	System	23 Nov 2020 22:47:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 15:49'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '24 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 2'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c'	System	24 Nov 2020 17:31:19
User entered 'Does not interfere with activity (2)'	System	24 Nov 2020 17:31:19

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c' User entered 'No (N)'	System	24 Nov 2020 17:31:19
	System	24 Nov 2020 17:31:19

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c' User entered 'No (N)'	System	24 Nov 2020 17:31:19
	System	24 Nov 2020 17:31:19

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c' User entered 'Does not interfere with activity (2)'	System	24 Nov 2020 17:31:19
	System	24 Nov 2020 17:31:19

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '29d4a129-98a4-488e-95d6-511067e25d2c' User entered '24 Nov 2020 12:31'	System	24 Nov 2020 17:31:19
	System	24 Nov 2020 17:31:19

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '24 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '25 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 3'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'e06d5a18-7e4e-4e6c-ba78-313b4596dd08' User entered 'None (1)'	System	25 Nov 2020 20:52:30
	System	25 Nov 2020 20:52:30

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:18', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'e06d5a18-7e4e-4e6c-ba78-313b4596dd08' User entered 'No (N)'	System	25 Nov 2020 20:52:30
	System	25 Nov 2020 20:52:30

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:21', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'e06d5a18-7e4e-4e6c-ba78-313b4596dd08' User entered 'No (N)'	System	25 Nov 2020 20:52:30
	System	25 Nov 2020 20:52:30

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'e06d5a18-7e4e-4e6c-ba78-313b4596dd08' User entered 'None (1)'	System	25 Nov 2020 20:52:30
	System	25 Nov 2020 20:52:30

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'e06d5a18-7e4e-4e6c-ba78-313b4596dd08' User entered '25 Nov 2020 15:52'	System	25 Nov 2020 20:52:30
	System	25 Nov 2020 20:52:30

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '25 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '26 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 4'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '165036d7-2d7f-423d-b1d5-2bc47980a543' User entered 'None (1)'	System	27 Nov 2020 13:12:50
	System	27 Nov 2020 13:12:50

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '165036d7-2d7f-423d-b1d5-2bc47980a543' User entered 'No (N)'	System	27 Nov 2020 13:12:50
	System	27 Nov 2020 13:12:50

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:42', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '165036d7-2d7f-423d-b1d5-2bc47980a543' User entered 'No (N)'	System	27 Nov 2020 13:12:50
	System	27 Nov 2020 13:12:50

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:44', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '165036d7-2d7f-423d-b1d5-2bc47980a543' User entered 'None (1)'	System	27 Nov 2020 13:12:50
	System	27 Nov 2020 13:12:50

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:47', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '165036d7-2d7f-423d-b1d5-2bc47980a543' User entered '27 Nov 2020 08:12'	System	27 Nov 2020 13:12:50
	System	27 Nov 2020 13:12:50

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '26 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '27 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 5'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '51079bef-0733-4f90-823c-c642fd90a503' User entered 'None (1)'	System	28 Nov 2020 16:30:20
	System	28 Nov 2020 16:30:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:11', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '51079bef-0733-4f90-823c-c642fd90a503' User entered 'No (N)'	System	28 Nov 2020 16:30:20
	System	28 Nov 2020 16:30:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '51079bef-0733-4f90-823c-c642fd90a503' User entered 'No (N)'	System	28 Nov 2020 16:30:20
	System	28 Nov 2020 16:30:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '51079bef-0733-4f90-823c-c642fd90a503' User entered 'None (1)'	System	28 Nov 2020 16:30:20
	System	28 Nov 2020 16:30:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:17', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '51079bef-0733-4f90-823c-c642fd90a503' User entered '28 Nov 2020 11:30'	System	28 Nov 2020 16:30:20
	System	28 Nov 2020 16:30:20

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '27 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '28 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 6'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b8aa8bc0-326f-46fa-9d99-536993693cc3' User entered 'None (1)'	System	29 Nov 2020 05:24:47
	System	29 Nov 2020 05:24:47

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:31', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b8aa8bc0-326f-46fa-9d99-536993693cc3' User entered 'No (N)'	System	29 Nov 2020 05:24:47
	System	29 Nov 2020 05:24:47

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b8aa8bc0-326f-46fa-9d99-536993693cc3' User entered 'No (N)'	System	29 Nov 2020 05:24:47
	System	29 Nov 2020 05:24:47

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:39', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b8aa8bc0-326f-46fa-9d99-536993693cc3' User entered 'None (1)'	System	29 Nov 2020 05:24:47
	System	29 Nov 2020 05:24:47

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b8aa8bc0-326f-46fa-9d99-536993693cc3' User entered '29 Nov 2020 00:24'	System	29 Nov 2020 05:24:47
	System	29 Nov 2020 05:24:47

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '28 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '29 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 7'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5c76e30a-0b9f-47e7-9f02-05b626211573' User entered 'None (1)'	System	29 Nov 2020 21:01:26
	System	29 Nov 2020 21:01:26

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:14', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5c76e30a-0b9f-47e7-9f02-05b626211573' User entered 'No (N)'	System	29 Nov 2020 21:01:26
	System	29 Nov 2020 21:01:26

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:17', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5c76e30a-0b9f-47e7-9f02-05b626211573' User entered 'No (N)'	System	29 Nov 2020 21:01:26
	System	29 Nov 2020 21:01:26

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:20', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5c76e30a-0b9f-47e7-9f02-05b626211573' User entered 'None (1)'	System	29 Nov 2020 21:01:26
	System	29 Nov 2020 21:01:26

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:23', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5c76e30a-0b9f-47e7-9f02-05b626211573' User entered '29 Nov 2020 16:01'	System	29 Nov 2020 21:01:26
	System	29 Nov 2020 21:01:26

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '29 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '30 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c' User entered 'None (0)'	System	23 Nov 2020 17:34:49
	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:26', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c' User entered 'None (0)'	System	23 Nov 2020 17:34:49
	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c' User entered 'None (0)'	System	23 Nov 2020 17:34:49
	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c' User entered 'None (0)'	System	23 Nov 2020 17:34:49
	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c' User entered 'None (0)'	System	23 Nov 2020 17:34:49
	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c' User entered 'None (0)'	System	23 Nov 2020 17:34:49
	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c' User entered 'No (N)'	System	23 Nov 2020 17:34:49
	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T12:34:44', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '70dcd23b-3720-4bfe-828c-603dfbd0308c' User entered '23 Nov 2020 12:34'	System	23 Nov 2020 17:34:49
	System	23 Nov 2020 17:34:49

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 12:24'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 14:54'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 1, after vaccination (at home)'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0' User entered 'None (0)'	System	23 Nov 2020 22:48:34
	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0'	System	23 Nov 2020 22:48:34
User entered 'No interference with activity (1)'	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:47', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0' User entered 'None (0)'	System	23 Nov 2020 22:48:34
	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0' User entered 'None (0)'	System	23 Nov 2020 22:48:34
	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0' User entered 'None (0)'	System	23 Nov 2020 22:48:34
	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:47:55', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0' User entered 'None (0)'	System	23 Nov 2020 22:48:34
	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:48:26', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0' User entered 'No (N)'	System	23 Nov 2020 22:48:34
	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-23T17:48:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '4330b896-f59b-4337-8e3b-099409c048d0' User entered '23 Nov 2020 17:48'	System	23 Nov 2020 22:48:34
	System	23 Nov 2020 22:48:34

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '23 Nov 2020 15:49'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '24 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 2'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	24 Nov 2020 17:32:20

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a' User entered 'Some interference with activity (2)'	System	24 Nov 2020 17:32:20
	System	24 Nov 2020 17:32:20

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a' User entered 'No interference with activity (1)'	System	24 Nov 2020 17:32:20
	System	24 Nov 2020 17:32:20

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a' User entered 'No interference with activity (1)'	System	24 Nov 2020 17:32:20
	System	24 Nov 2020 17:32:20

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:31:59', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	24 Nov 2020 17:32:20

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:32:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a'	System	24 Nov 2020 17:32:20
User entered 'No interference with activity (1)'	System	24 Nov 2020 17:32:20

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:32:11', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a' User entered 'No (N)'	System	24 Nov 2020 17:32:20
	System	24 Nov 2020 17:32:20

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-24T12:32:18', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a3e32140-b62e-49a4-a544-964ca2cf344a' User entered '24 Nov 2020 12:32'	System	24 Nov 2020 17:32:20
	System	24 Nov 2020 17:32:20

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '24 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '25 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 3'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '25d5a9a1-7456-4b8a-b6dc-f7493ed33645' User entered 'None (0)'	System	25 Nov 2020 20:53:04
	System	25 Nov 2020 20:53:04

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '25d5a9a1-7456-4b8a-b6dc-f7493ed33645' User entered 'None (0)'	System	25 Nov 2020 20:53:04
	System	25 Nov 2020 20:53:04

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '25d5a9a1-7456-4b8a-b6dc-f7493ed33645' User entered 'None (0)'	System	25 Nov 2020 20:53:04
	System	25 Nov 2020 20:53:04

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '25d5a9a1-7456-4b8a-b6dc-f7493ed33645' User entered 'None (0)'	System	25 Nov 2020 20:53:04
	System	25 Nov 2020 20:53:04

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:40', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '25d5a9a1-7456-4b8a-b6dc-f7493ed33645' User entered 'None (0)'	System	25 Nov 2020 20:53:04
	System	25 Nov 2020 20:53:04

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '25d5a9a1-7456-4b8a-b6dc-f7493ed33645' User entered 'None (0)'	System	25 Nov 2020 20:53:04
	System	25 Nov 2020 20:53:04

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:52:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '25d5a9a1-7456-4b8a-b6dc-f7493ed33645' User entered 'No (N)'	System	25 Nov 2020 20:53:04
	System	25 Nov 2020 20:53:04

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-25T15:53:01', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '25d5a9a1-7456-4b8a-b6dc-f7493ed33645' User entered '25 Nov 2020 15:53'	System	25 Nov 2020 20:53:04
	System	25 Nov 2020 20:53:04

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '25 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '26 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 4'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2228930b-f751-4a12-b2eb-eeb3b84349cb' User entered 'None (0)'	System	27 Nov 2020 13:13:06
	System	27 Nov 2020 13:13:06

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:51', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2228930b-f751-4a12-b2eb-eeb3b84349cb' User entered 'None (0)'	System	27 Nov 2020 13:13:06
	System	27 Nov 2020 13:13:06

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2228930b-f751-4a12-b2eb-eeb3b84349cb' User entered 'None (0)'	System	27 Nov 2020 13:13:06
	System	27 Nov 2020 13:13:06

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:55', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2228930b-f751-4a12-b2eb-eeb3b84349cb' User entered 'None (0)'	System	27 Nov 2020 13:13:06
	System	27 Nov 2020 13:13:06

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:57', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2228930b-f751-4a12-b2eb-eeb3b84349cb' User entered 'None (0)'	System	27 Nov 2020 13:13:06
	System	27 Nov 2020 13:13:06

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:12:58', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2228930b-f751-4a12-b2eb-eeb3b84349cb' User entered 'None (0)'	System	27 Nov 2020 13:13:06
	System	27 Nov 2020 13:13:06

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:13:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2228930b-f751-4a12-b2eb-eeb3b84349cb' User entered 'No (N)'	System	27 Nov 2020 13:13:06
	System	27 Nov 2020 13:13:06

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-27T08:13:02', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2228930b-f751-4a12-b2eb-eeb3b84349cb' User entered '27 Nov 2020 08:13'	System	27 Nov 2020 13:13:06
	System	27 Nov 2020 13:13:06

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '26 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '27 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 5'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:21', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c30e09a4-27da-43f5-9d92-5d247074d235' User entered 'None (0)'	System	28 Nov 2020 16:30:39
	System	28 Nov 2020 16:30:39

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:23', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c30e09a4-27da-43f5-9d92-5d247074d235' User entered 'None (0)'	System	28 Nov 2020 16:30:39
	System	28 Nov 2020 16:30:39

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:24', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c30e09a4-27da-43f5-9d92-5d247074d235' User entered 'None (0)'	System	28 Nov 2020 16:30:39
	System	28 Nov 2020 16:30:39

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c30e09a4-27da-43f5-9d92-5d247074d235' User entered 'None (0)'	System	28 Nov 2020 16:30:39
	System	28 Nov 2020 16:30:39

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c30e09a4-27da-43f5-9d92-5d247074d235' User entered 'None (0)'	System	28 Nov 2020 16:30:39
	System	28 Nov 2020 16:30:39

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c30e09a4-27da-43f5-9d92-5d247074d235' User entered 'None (0)'	System	28 Nov 2020 16:30:39
	System	28 Nov 2020 16:30:39

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:31', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c30e09a4-27da-43f5-9d92-5d247074d235' User entered 'No (N)'	System	28 Nov 2020 16:30:39
	System	28 Nov 2020 16:30:39

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-28T11:30:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c30e09a4-27da-43f5-9d92-5d247074d235' User entered '28 Nov 2020 11:30'	System	28 Nov 2020 16:30:39
	System	28 Nov 2020 16:30:39

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '27 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '28 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 6'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9f07118c-616e-4812-b4c0-3f9649172ded' User entered 'None (0)'	System	29 Nov 2020 05:25:17
	System	29 Nov 2020 05:25:17

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:53', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9f07118c-616e-4812-b4c0-3f9649172ded' User entered 'None (0)'	System	29 Nov 2020 05:25:17
	System	29 Nov 2020 05:25:17

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:24:55', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9f07118c-616e-4812-b4c0-3f9649172ded' User entered 'None (0)'	System	29 Nov 2020 05:25:17
	System	29 Nov 2020 05:25:17

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:25:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9f07118c-616e-4812-b4c0-3f9649172ded' User entered 'None (0)'	System	29 Nov 2020 05:25:17
	System	29 Nov 2020 05:25:17

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:25:02', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9f07118c-616e-4812-b4c0-3f9649172ded' User entered 'None (0)'	System	29 Nov 2020 05:25:17
	System	29 Nov 2020 05:25:17

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:25:05', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9f07118c-616e-4812-b4c0-3f9649172ded' User entered 'None (0)'	System	29 Nov 2020 05:25:17
	System	29 Nov 2020 05:25:17

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:25:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9f07118c-616e-4812-b4c0-3f9649172ded' User entered 'No (N)'	System	29 Nov 2020 05:25:17
	System	29 Nov 2020 05:25:17

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:25:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9f07118c-616e-4812-b4c0-3f9649172ded' User entered '29 Nov 2020 00:25'	System	29 Nov 2020 05:25:17
	System	29 Nov 2020 05:25:17

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '28 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '29 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
Data entry locked.	(b) (4), (b) (6) System	23 Nov 2020 17:12:03
User entered 'Day 7'	System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:27', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2972e1b-ee25-48ee-83f6-40ad1736a04e' User entered 'None (0)'	System	29 Nov 2020 21:01:50
	System	29 Nov 2020 21:01:50

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:30', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2972e1b-ee25-48ee-83f6-40ad1736a04e' User entered 'None (0)'	System	29 Nov 2020 21:01:50
	System	29 Nov 2020 21:01:50

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2972e1b-ee25-48ee-83f6-40ad1736a04e' User entered 'None (0)'	System	29 Nov 2020 21:01:50
	System	29 Nov 2020 21:01:50

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2972e1b-ee25-48ee-83f6-40ad1736a04e' User entered 'None (0)'	System	29 Nov 2020 21:01:50
	System	29 Nov 2020 21:01:50

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2972e1b-ee25-48ee-83f6-40ad1736a04e' User entered 'None (0)'	System	29 Nov 2020 21:01:50
	System	29 Nov 2020 21:01:50

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:39', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2972e1b-ee25-48ee-83f6-40ad1736a04e' User entered 'None (0)'	System	29 Nov 2020 21:01:50
	System	29 Nov 2020 21:01:50

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:42', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2972e1b-ee25-48ee-83f6-40ad1736a04e' User entered 'No (N)'	System	29 Nov 2020 21:01:50
	System	29 Nov 2020 21:01:50

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T16:01:48', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'd2972e1b-ee25-48ee-83f6-40ad1736a04e' User entered '29 Nov 2020 16:01'	System	29 Nov 2020 21:01:50
	System	29 Nov 2020 21:01:50

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '29 Nov 2020 12:00'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:53:37

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	04 Mar 2021 21:38:27
User entered '30 Nov 2020 11:59'	(b) (4), (b) (6) System	23 Nov 2020 17:12:03

US3022103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:50
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '30 Nov 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:50
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:50
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:50

US3022103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:49:58
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'I'	(b) (4), (b) (6) System	02 Dec 2020 14:49:58

US3022103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	08 Dec 2020 21:36:27
	(b) (4)	

US3022103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '08 Dec 2020'	Chevon Roberts (b) (4)	08 Dec 2020 21:36:27
	(b) (4)	

US3022103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	Chevon Roberts (b) (4)	08 Dec 2020 21:36:27
	(b) (4)	

US3022103

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	08 Dec 2020 21:36:27
	(b) (4)	

US3022103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	Chevon Roberts (b) (4)	08 Dec 2020 21:36:31
	(b) (4)	

US3022103

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'I'	(b) (4), (b) (6) System	08 Dec 2020 21:36:31

US3022103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 14:44:18
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '14 Dec 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 14:44:18
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 14:44:18
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 14:44:18
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	15 Dec 2020 14:44:26

US3022103

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'I'	(b) (4), (b) (6) System	15 Dec 2020 14:44:26

US3022103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:19
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '21 Dec 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:19
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[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 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:19
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'VISIT3'	(b) (4), (b) (6) System	23 Dec 2020 16:55:19

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '21 Dec 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '10:52'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered '21 Dec 2020 10:52'	(b) (4), (b) (6) System	23 Dec 2020 16:55:48

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '36.9' C	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '74'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'bpm'	(b) (4), (b) (6) System	23 Dec 2020 16:55:48

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '18'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'breaths/min'	(b) (4), (b) (6) System	23 Dec 2020 16:55:48

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '106'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'mmHg'	(b) (4), (b) (6) System	23 Dec 2020 16:55:48

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '75'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:48
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'mmHg'	(b) (4), (b) (6) System	23 Dec 2020 16:55:48

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:53:37

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:58
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:53:37

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '21 Dec 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:55:58
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:56:12
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '21 Dec 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:56:12
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '11:19'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:56:12
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered '21 Dec 2020 11:19'	(b) (4), (b) (6) System	23 Dec 2020 16:56:12

US3022103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	23 Dec 2020 16:56:17
	(b) (4), (b) (6)	

US3022103

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'I'	(b) (4), (b) (6) System	23 Dec 2020 16:56:17

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered 'Day 64'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:52
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' answered with 'THERE IS NO AE TO ENTER FOR THIS.' (Site from DM).	Morgan Deal (b) (4) (b) (4)	08 Mar 2021 20:03:30
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 08:01:10
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered 'Yes (Y)'	System	01 Oct 2020 18:28:54

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cddb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered 'No (N)'	System	01 Oct 2020 18:28:54

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:20', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	(b) (4), (b) (6) System	01 Oct 2020 18:28:54
User entered 'No (N)'	System	01 Oct 2020 18:28:54

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:25', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166'	System	01 Oct 2020 18:28:54
User entered 'Yes (Y)'	System	01 Oct 2020 18:28:54

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Please 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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cddb18-8fc8-4bc0-933e-59ed2e6ae166'	(b) (4), (b) (6) System	01 Oct 2020 18:28:54
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Oct 2020 18:28:54

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-01T14:28:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04cbdb18-8fc8-4bc0-933e-59ed2e6ae166' User entered '01 Oct 2020 14:28:43'	(b) (4), (b) (6) System	01 Oct 2020 18:28:54
	System	01 Oct 2020 18:28:54

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 71'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

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Please 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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

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[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

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[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

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[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Please 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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

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[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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please 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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 20:27:08

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

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TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered 'Day 78'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-14T11:43:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a00a087c-25db-4178-8da8-2470a1af6f28' User entered 'No (N)'	System	14 Oct 2020 15:43:16
	System	14 Oct 2020 15:43:16

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-14T11:43:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a00a087c-25db-4178-8da8-2470a1af6f28'	System	14 Oct 2020 15:43:16
User entered 'No (N)'	System	14 Oct 2020 15:43:16

US3022103

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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-14T11:43:13', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a00a087c-25db-4178-8da8-2470a1af6f28' User entered '14 Oct 2020 11:43:13'	(b) (4), (b) (6) System	14 Oct 2020 15:43:16
	System	14 Oct 2020 15:43:16

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered 'Day 92'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

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[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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-31T18:56:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '49af159d-3414-42a8-bcd9-4879bff199e1' User entered 'No (N)'	(b) (4), (b) (6) System	31 Oct 2020 22:56:25
	System	31 Oct 2020 22:56:25

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Have you been exposed to someone with 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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-31T18:56:05', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '49af159d-3414-42a8-bcd9-4879bff199e1' User entered 'No (N)'	System	31 Oct 2020 22:56:25
	System	31 Oct 2020 22:56:25

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-10-31T18:56:20', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '49af159d-3414-42a8-bcd9-4879bff199e1' User entered '31 Oct 2020 18:56:20'	(b) (4), (b) (6) System	31 Oct 2020 22:56:25
	System	31 Oct 2020 22:56:25

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered 'Day 99'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-06T12:03:57', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5970e9e-5377-457d-9fab-1040835cc982'	System	06 Nov 2020 17:05:33
User entered 'No (N)'	System	06 Nov 2020 17:05:33

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-06T12:04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5970e9e-5377-457d-9fab-1040835cc982'	System	06 Nov 2020 17:05:33
User entered 'No (N)'	System	06 Nov 2020 17:05:33

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-06T12:04:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5970e9e-5377-457d-9fab-1040835cc982' User entered '06 Nov 2020 12:04:03'	System	06 Nov 2020 17:05:33
	System	06 Nov 2020 17:05:33

US3022103

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered 'Day 106'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-11T00:01:34', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'dcd7ef02-fc2f-482c-990c-29751bf46c34'	System	11 Nov 2020 05:01:47
User entered 'No (N)'	System	11 Nov 2020 05:01:47

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-11T00:01:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'dcd7ef02-fc2f-482c-990c-29751bf46c34'	System	11 Nov 2020 05:01:47
User entered 'No (N)'	System	11 Nov 2020 05:01:47

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-11T00:01:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'dcd7ef02-fc2f-482c-990c-29751bf46c34' User entered '11 Nov 2020 00:01:41'	(b) (4), (b) (6) System	11 Nov 2020 05:01:47
	System	11 Nov 2020 05:01:47

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 15:00:55
Data entry locked.	(b) (4), (b) (6)	
	System	31 Jul 2020 20:27:08
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34
Data entry locked.	System	31 Jul 2020 20:27:08
User entered 'Day 113'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please 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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Please 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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Please 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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 20:27:08

US3022103

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
DataPoint activated (WR#5335027)	(b) (4), (b) (6) System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 11:04:34
Data entry locked.	System	31 Jul 2020 20:27:08
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 20:27:08

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-22T22:18:01', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '08e8a2aa-3b86-4adf-aea8-4116465f7086'	System	23 Nov 2020 03:18:09
User entered 'No (N)'	System	23 Nov 2020 03:18:09

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-22T22:18:03', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '08e8a2aa-3b86-4adf-aea8-4116465f7086' User entered 'No (N)'	System	23 Nov 2020 03:18:09

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-22T22:18:08', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '08e8a2aa-3b86-4adf-aea8-4116465f7086'	System	23 Nov 2020 03:18:09
User entered '22 Nov 2020 22:18:08'	System	23 Nov 2020 03:18:09

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:25:22', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1b931038-7079-4b14-ae6b-be87de90533e'	System	29 Nov 2020 05:25:39
User entered 'No (N)'	System	29 Nov 2020 05:25:39

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:25:33', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1b931038-7079-4b14-ae6b-be87de90533e' User entered 'No (N)'	System	29 Nov 2020 05:25:39

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-11-29T00:25:37', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1b931038-7079-4b14-ae6b-be87de90533e' User entered '29 Nov 2020 00:25:37'	System	29 Nov 2020 05:25:39
	System	29 Nov 2020 05:25:39

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-06T00:01:51', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ba542c40-1467-41bd-9ebc-5832df747d1b' User entered 'No (N)'	System	06 Dec 2020 05:02:21
	System	06 Dec 2020 05:02:21

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-06T00:01:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ba542c40-1467-41bd-9ebc-5832df747d1b' User entered 'No (N)'	System	06 Dec 2020 05:02:21
	System	06 Dec 2020 05:02:21

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-06T00:02:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'ba542c40-1467-41bd-9ebc-5832df747d1b' User entered '06 Dec 2020 00:02:00'	System	06 Dec 2020 05:02:21
	System	06 Dec 2020 05:02:21

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-13T00:01:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04aa582e-200c-4073-91be-17ac9dc8cc1d' User entered 'No (N)'	System	13 Dec 2020 05:02:00
	System	13 Dec 2020 05:02:00

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-13T00:01:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04aa582e-200c-4073-91be-17ac9dc8cc1d' User entered 'No (N)'	System	13 Dec 2020 05:02:00
	System	13 Dec 2020 05:02:00

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-13T00:01:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '04aa582e-200c-4073-91be-17ac9dc8cc1d' User entered '13 Dec 2020 00:01:38'	System	13 Dec 2020 05:02:00
	System	13 Dec 2020 05:02:00

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-22T12:06:54', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c949bd00-6fa5-4a11-980d-4b79e2b25591' User entered 'No (N)'	System	22 Dec 2020 17:07:02
	System	22 Dec 2020 17:07:02

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-22T12:06:56', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c949bd00-6fa5-4a11-980d-4b79e2b25591' User entered 'No (N)'	System	22 Dec 2020 17:07:02
	System	22 Dec 2020 17:07:02

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-22T12:07:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c949bd00-6fa5-4a11-980d-4b79e2b25591' User entered '22 Dec 2020 12:07:00'	System	22 Dec 2020 17:07:02
	System	22 Dec 2020 17:07:02

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-27T11:39:04', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '43b0376e-1713-4e8f-9c39-0b8c52206fc9' User entered 'No (N)'	System	27 Dec 2020 16:39:11
	System	27 Dec 2020 16:39:11

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-27T11:39:06', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '43b0376e-1713-4e8f-9c39-0b8c52206fc9' User entered 'No (N)'	System	27 Dec 2020 16:39:11
	System	27 Dec 2020 16:39:11

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2020-12-27T11:39:09', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '43b0376e-1713-4e8f-9c39-0b8c52206fc9' User entered '27 Dec 2020 11:39:09'	System	27 Dec 2020 16:39:11
	System	27 Dec 2020 16:39:11

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-03T01:01:07', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5721e16c-537d-4c4c-a253-3399c128023c' User entered 'No (N)'	System	03 Jan 2021 06:01:25
	System	03 Jan 2021 06:01:25

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-03T01:01:10', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5721e16c-537d-4c4c-a253-3399c128023c'	System	03 Jan 2021 06:01:25
User entered 'No (N)'	System	03 Jan 2021 06:01:25

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-03T01:01:15', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5721e16c-537d-4c4c-a253-3399c128023c' User entered '03 Jan 2021 01:01:15'	System	03 Jan 2021 06:01:25
	System	03 Jan 2021 06:01:25

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-10T09:00:43', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2a629ec9-718a-425f-83b0-5abda023fd96'	System	10 Jan 2021 14:00:52
User entered 'No (N)'	System	10 Jan 2021 14:00:52

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-10T09:00:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2a629ec9-718a-425f-83b0-5abda023fd96'	System	10 Jan 2021 14:00:52
User entered 'No (N)'	System	10 Jan 2021 14:00:52

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-10T09:00:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2a629ec9-718a-425f-83b0-5abda023fd96'	System	10 Jan 2021 14:00:52
User entered '10 Jan 2021 09:00:50'	System	10 Jan 2021 14:00:52

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-17T00:52:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d993331-3c77-4d7e-9eb3-9e0cce1a974'	System	17 Jan 2021 05:52:25
User entered 'No (N)'	System	17 Jan 2021 05:52:25

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-17T00:52:15', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d993331-3c77-4d7e-9eb3-9e0cce1a974'	System	17 Jan 2021 05:52:25
User entered 'No (N)'	System	17 Jan 2021 05:52:25

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-17T00:52:20', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '1d993331-3c77-4d7e-9eb3-9e0cce1a974'	System	17 Jan 2021 05:52:25
User entered '17 Jan 2021 00:52:20'	System	17 Jan 2021 05:52:25

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-26T18:00:36', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5ba94146-2b04-4874-9b1c-98843825d00d'	System	27 Jan 2021 00:38:34
User entered 'No (N)'	System	27 Jan 2021 00:38:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-26T18:00:38', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5ba94146-2b04-4874-9b1c-98843825d00d'	System	27 Jan 2021 00:38:34
User entered 'No (N)'	System	27 Jan 2021 00:38:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-26T18:00:41', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5ba94146-2b04-4874-9b1c-98843825d00d' User entered '26 Jan 2021 18:00:41'	System	27 Jan 2021 00:38:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-31T00:01:29', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d010705-4412-4aee-86fa-d06779561e8b' User entered 'No (N)'	System	31 Jan 2021 05:01:57
	System	31 Jan 2021 05:01:57

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-31T00:01:32', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d010705-4412-4aee-86fa-d06779561e8b' User entered 'No (N)'	System	31 Jan 2021 05:01:57

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-01-31T00:01:35', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '6d010705-4412-4aee-86fa-d06779561e8b' User entered '31 Jan 2021 00:01:35'	System	31 Jan 2021 05:01:57
	System	31 Jan 2021 05:01:57

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-10T18:02:46', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b43be742-a3a8-41ee-96df-ec8676b10d67'	System	10 Feb 2021 23:07:01
User entered 'No (N)'	System	10 Feb 2021 23:07:01

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-10T18:02:49', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b43be742-a3a8-41ee-96df-ec8676b10d67'	System	10 Feb 2021 23:07:01
User entered 'No (N)'	System	10 Feb 2021 23:07:01

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-10T18:02:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'b43be742-a3a8-41ee-96df-ec8676b10d67'	System	10 Feb 2021 23:07:01
User entered '10 Feb 2021 18:02:52'	System	10 Feb 2021 23:07:01

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-16T12:00:11', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '061e8197-ccc6-4859-b3a8-2b19fd550dee' User entered 'No (N)'	System	16 Feb 2021 17:00:30
	System	16 Feb 2021 17:00:30

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-16T12:00:12', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '061e8197-ccc6-4859-b3a8-2b19fd550dee' User entered 'No (N)'	System	16 Feb 2021 17:00:30
	System	16 Feb 2021 17:00:30

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-16T12:00:16', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '061e8197-ccc6-4859-b3a8-2b19fd550dee' User entered '16 Feb 2021 12:00:16'	System	16 Feb 2021 17:00:30
	System	16 Feb 2021 17:00:30

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-25T07:23:50', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '463cea55-08fa-48a3-bdad-8eead962f42e' User entered 'No (N)'	System	25 Feb 2021 12:23:58
	System	25 Feb 2021 12:23:58

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-25T07:23:52', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '463cea55-08fa-48a3-bdad-8eead962f42e' User entered 'No (N)'	System	25 Feb 2021 12:23:58
	System	25 Feb 2021 12:23:58

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-02-25T07:23:55', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '463cea55-08fa-48a3-bdad-8eead962f42e' User entered '25 Feb 2021 07:23:55'	System	25 Feb 2021 12:23:58
	System	25 Feb 2021 12:23:58

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-02T12:00:44-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5541dbfb-459e-40e1-a598-71db12d766bf' User entered 'No (N)'	System	02 Mar 2021 17:02:38
	System	02 Mar 2021 17:02:38

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-02T12:00:47-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5541dbfb-459e-40e1-a598-71db12d766bf' User entered 'No (N)'	System	02 Mar 2021 17:02:38

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-02T12:00:49-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '5541dbfb-459e-40e1-a598-71db12d766bf' User entered '02 Mar 2021 17:00:49'	System	02 Mar 2021 17:02:38
	System	02 Mar 2021 17:02:38

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-10T19:05:01-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '8aaaa57b-dbd4-4ae6-8ecc-c312db861613'	System	11 Mar 2021 00:08:30
User entered 'No (N)'	System	11 Mar 2021 00:08:30

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-10T19:05:07-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '8aaaa57b-dbd4-4ae6-8ecc-c312db861613'	System	11 Mar 2021 00:08:30
User entered 'No (N)'	System	11 Mar 2021 00:08:30

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-10T19:05:10-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '8aaaa57b-dbd4-4ae6-8ecc-c312db861613'	System	11 Mar 2021 00:08:30
User entered '10 Mar 2021 19:05:10'	System	11 Mar 2021 00:08:30

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-14T01:04:21-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9a91d354-4686-4e2d-ab37-43d0f9136a8c'	System	18 Mar 2021 16:34:01
User entered 'No (N)'	System	18 Mar 2021 16:34:01

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-14T01:04:26-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9a91d354-4686-4e2d-ab37-43d0f9136a8c'	System	18 Mar 2021 16:34:01
User entered 'No (N)'	System	18 Mar 2021 16:34:01

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-14T01:04:29-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '9a91d354-4686-4e2d-ab37-43d0f9136a8c'	System	18 Mar 2021 16:34:01
User entered '14 Mar 2021 01:04:29'	System	18 Mar 2021 16:34:01

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-21T00:02:41-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2d703154-15c7-4cb1-9c81-1faa41749e22'	System	21 Mar 2021 04:03:29
User entered 'No (N)'	System	21 Mar 2021 04:03:29

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-21T00:02:44-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2d703154-15c7-4cb1-9c81-1faa41749e22'	System	21 Mar 2021 04:03:29
User entered 'No (N)'	System	21 Mar 2021 04:03:29

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-21T00:02:47-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2d703154-15c7-4cb1-9c81-1faa41749e22' User entered '21 Mar 2021 00:02:47'	System	21 Mar 2021 04:03:29
	System	21 Mar 2021 04:03:29

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-28T01:33:27-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c0d88367-5fcf-4874-8c55-6406e09df44a'	System	28 Mar 2021 05:33:38
User entered 'No (N)'	System	28 Mar 2021 05:33:38

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-28T01:33:29-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c0d88367-5fcf-4874-8c55-6406e09df44a'	System	28 Mar 2021 05:33:38
User entered 'No (N)'	System	28 Mar 2021 05:33:38

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-28T01:33:33-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'c0d88367-5fcf-4874-8c55-6406e09df44a' User entered '28 Mar 2021 01:33:33'	System	28 Mar 2021 05:33:38
	System	28 Mar 2021 05:33:38

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-04T00:02:59-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '56fb19bc-7d1e-4fe1-9dc1-dfc8d8097dd2'	System	04 Apr 2021 04:04:13
User entered 'No (N)'	System	04 Apr 2021 04:04:13

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-04T00:03:04-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '56fb19bc-7d1e-4fe1-9dc1-dfc8d8097dd2'	System	04 Apr 2021 04:04:13
User entered 'No (N)'	System	04 Apr 2021 04:04:13

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-04T00:03:07-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '56fb19bc-7d1e-4fe1-9dc1-dfc8d8097dd2'	System	04 Apr 2021 04:04:13
User entered '04 Apr 2021 00:03:07'	System	04 Apr 2021 04:04:13

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-11T13:22:09-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'cab93201-38e5-408e-ae57-aa8ef4f165d8'	System	11 Apr 2021 17:22:17
User entered 'No (N)'	System	11 Apr 2021 17:22:17

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-11T13:22:11-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'cab93201-38e5-408e-ae57-aa8ef4f165d8'	System	11 Apr 2021 17:22:17
User entered 'No (N)'	System	11 Apr 2021 17:22:17

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-11T13:22:14-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'cab93201-38e5-408e-ae57-aa8ef4f165d8'	System	11 Apr 2021 17:22:17
User entered '11 Apr 2021 13:22:14'	System	11 Apr 2021 17:22:17

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-18T00:15:46-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '868534af-ece5-4337-be62-b40041a35281' User entered 'No (N)'	System	18 Apr 2021 04:15:54

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-18T00:15:48-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '868534af-ece5-4337-be62-b40041a35281' User entered 'No (N)'	System	18 Apr 2021 04:15:54

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-18T00:15:51-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '868534af-ece5-4337-be62-b40041a35281' User entered '18 Apr 2021 00:15:51'	System	18 Apr 2021 04:15:54
	System	18 Apr 2021 04:15:54

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-25T00:02:16-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5965275-e197-4dbb-98f5-cb8b63d6b251'	System	25 Apr 2021 04:03:07
User entered 'No (N)'	System	25 Apr 2021 04:03:07

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-25T00:02:19-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5965275-e197-4dbb-98f5-cb8b63d6b251'	System	25 Apr 2021 04:03:07
User entered 'No (N)'	System	25 Apr 2021 04:03:07

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-04-25T00:02:22-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: 'a5965275-e197-4dbb-98f5-cb8b63d6b251'	System	25 Apr 2021 04:03:07
User entered '25 Apr 2021 00:02:22'	System	25 Apr 2021 04:03:07

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-05-03T17:22:29-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '8e470f3a-ec41-4f04-ae84-6a43e0e8c3b8'	System	03 May 2021 21:22:36
User entered 'No (N)'	System	03 May 2021 21:22:36

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Have you been exposed to someone with 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 (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-05-03T17:22:30-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '8e470f3a-ec41-4f04-ae84-6a43e0e8c3b8'	System	03 May 2021 21:22:36
User entered 'No (N)'	System	03 May 2021 21:22:36

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-05-03T17:22:33-04:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '8e470f3a-ec41-4f04-ae84-6a43e0e8c3b8'	System	03 May 2021 21:22:36
User entered '03 May 2021 17:22:33'	System	03 May 2021 21:22:36

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 11:04:34

US3022103

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:53:37

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 11:04:34
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 11:04:34

US3022103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:53:37

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) (b) (4), (b) (6)	24 Apr 2021 08:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-02T12:00:59-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2ca7f2c8-2b56-4606-93fc-c4659c2cef47' User entered 'No (N)'	(b) (4), (b) (6) System	02 Mar 2021 17:03:25
	System	02 Mar 2021 17:03:25

US3022103

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:53:37

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	24 Apr 2021 08:42:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (94A63887-DC95-4250-B1F2-4B7EF4DFC71C)', Time: '2021-03-02T12:01:03-05:00', User OID: 'PatientReportedOutcome (US3022103)', ODM File OID: '2ca7f2c8-2b56-4606-93fc-c4659c2cef47' User entered '02 Mar 2021 17:01:03'	System	02 Mar 2021 17:03:25
	System	02 Mar 2021 17:03:25

US3022103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 09:52:28
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:14:41
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:09:24

US3022103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 09:52:28
User closed query 'Per CDM (RQ): Please note Safety Day 85 should be after Day 29.Safety Call Day 85 happens on 85th day after visit 1, it cannot be before day 29. Day 85 should happen after Day 29. Thanks ' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Apr 2021 16:33:57
Query 'Per CDM (RQ): Please note Safety Day 85 should be after Day 29.Safety Call Day 85 happens on 85th day after visit 1, it cannot be before day 29. Day 85 should happen after Day 29. Thanks ' answered with 'visit 2 date was out of range ' (Site from DM).	Paul Bradley (b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	13 Apr 2021 22:14:41 09 Apr 2021 13:12:28
User opened query 'Per CDM (RQ): Please note Safety Day 85 should be after Day 29.Safety Call Day 85 happens on 85th day after visit 1, it cannot be before day 29. Day 85 should happen after Day 29. Thanks ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 06:25:50
User closed query 'Per CDM: Please review the date of Safety Call Day 85 since it is prior to Visit 2 Day 29 (23 Nov 2020). Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 06:25:50
Query 'Per CDM: Please review the date of Safety Call Day 85 since it is prior to Visit 2 Day 29 (23 Nov 2020). Review and update as appropriate. ' answered with 'this is correct ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	31 Mar 2021 17:08:00
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)	30 Mar 2021 14:53:02
User opened query 'Per CDM: Please review the date of Safety Call Day 85 since it is prior to Visit 2 Day 29 (23 Nov 2020). Review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	30 Mar 2021 14:52:59
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)	29 Mar 2021 14:09:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

1548 of 2061

US3022103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
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	29 Mar 2021 14:09:24
User entered '30 Oct 2020'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:09:24
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 09:52:28
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:14:41
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:09:24

US3022103

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	30 Apr 2021 09:52:28
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:14:41
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:09:24

US3022103

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 22:32:19
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:01:46
User entered 'I'	(b) (4), (b) (6) System	18 Feb 2021 22:32:19

US3022103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:17:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 22:32:29
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:17:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '18 Feb 2021'	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 22:32:29
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:17:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 22:32:29
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:17:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 22:32:29
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:17:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	18 Feb 2021 22:32:34
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 06:17:50
User entered 'I'	System	18 Feb 2021 22:32:34

US3022103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:14:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:07:50
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:48
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:14:41
User closed query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Mar 2021 14:51:12
Query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 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) (b) (4), (b) (6)	29 Mar 2021 14:07:58
User opened query 'Safety Call Day 149 'Date of Contact or Contact Attempt' is less than 117 days or greater than 123 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile or clarify.' (Site from System).	System	29 Mar 2021 14:07:50
User entered '29 Mar 2021'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:07:50

US3022103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:14:41
	(b) (4)	
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:07:50
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:14:41
	(b) (4)	
User entered empty.	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:07:50
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:48
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:14:41
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	29 Mar 2021 14:08:04
	(b) (4), (b) (6)	

US3022103

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 01:01:48
User entered 'I'	(b) (4), (b) (6) System	29 Mar 2021 14:08:04

US3022103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 18:55:38

US3022103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:16:20
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 18:55:38

US3022103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:16:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 18:55:38

US3022103

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:53:37

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:16:20
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 18:55:38

US3022103

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:16:20
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Apr 2021 18:55:42

US3022103

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:53:37

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 18:55:42

US3022103

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

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:19

US3022103

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

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '12 Jan 2021'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:19
	(b) (4), (b) (6)	

US3022103

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

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:19

US3022103

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

Form: Visit Date

Generated On: 09 Jun 2021 14:53:37

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	12 Jan 2021 15:10:19

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Date of updated informed consent \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:42

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:14:41
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 13:10:02
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:01:45

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:42

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	13 Apr 2021 22:14:41
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) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Apr 2021 12:20:06
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) (b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 13:10:24
User entered 'Amendment 6 or later (Amendment 6 or later)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 13:10:02
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) (b) (4), (b) (6) (b) (4), (b) (6)	09 Apr 2021 10:44:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:01:45

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:42

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:42

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:11:31
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:42
	(b) (4), (b) (6)	

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	System	20 Jan 2021 11:11:31
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:42
	(b) (4), (b) (6)	

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:10:42

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User entered empty.	(b) (4), (b) (6) System	12 Jan 2021 15:10:42

US3022103

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

Form: Unblinding

Generated On: 09 Jun 2021 14:53:37

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:51
User entered empty.	(b) (4), (b) (6) System	12 Jan 2021 15:10:42

US3022103

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:11:19
	(b) (4), (b) (6)	

US3022103

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:11:19

US3022103

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '09:36'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:11:19
	(b) (4), (b) (6)	

US3022103

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:53:37

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:44
User entered '12 Jan 2021 09:36'	(b) (4), (b) (6) System	12 Jan 2021 15:11:19

US3022103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:37

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:11:35

US3022103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:37

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:44
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '12 Jan 2021'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:11:35

US3022103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:37

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:44
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '09:44'	(b) (4), (b) (6) (b) (4), (b) (6)	12 Jan 2021 15:11:35
	(b) (4), (b) (6)	

US3022103

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:53:37

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:46:44
User entered '12 Jan 2021 09:44'	(b) (4), (b) (6) System	12 Jan 2021 15:11:35

US3022103

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:53:37

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 06:03:29
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:24:45
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 19:59:11
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 19:47:01
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:55:20

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:25:30
	(b) (4), (b) (6)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Neck pain, LLT: Neck pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:58:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	17 Aug 2020 22:58:17
Data point term sent to Coder	System	17 Aug 2020 22:57:32
User entered 'NECK PAIN'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:57:02

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:33
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:35
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:25:38
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:04:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	31 Aug 2020 15:04:01
User entered 'No (N)' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:04:01
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Aug 2020 15:03:56
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:03:56
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:40
	(b) (4), (b) (6)	
User entered '14 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:42
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 22:57:02

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:43
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:44
	(b) (4), (b) (6)	
User entered '17 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:47
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
User entered empty.	(b) (4), (b) (6) System	17 Aug 2020 22:57:02

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:49
	(b) (4), (b) (6)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:25:53
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 22:59:13
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Aug 2020 22:59:13
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	17 Aug 2020 22:59:13
User opened query 'Data is required. Please complete.' (Site from System).	System	17 Aug 2020 22:57:02
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:56
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:57
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:25:59
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:03
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:05
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:07
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:09
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:10
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:12
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:13
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:15
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:17
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered 'None (NONE)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:20
	(b) (4), (b) (6)	
User entered '0' reason for change: Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 15:03:56
	(b) (4)	
User entered '1'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:22
	(b) (4), (b) (6)	
User entered '1' reason for change: Data Entry Error	Stella Yoon (b) (4)	31 Aug 2020 15:03:56
	(b) (4)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:25
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:27
	(b) (4), (b) (6)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[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 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:29
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:26:31
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:57:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
Amendment Manager: User entered '0'	(b) (4), (b) (6)	
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:32
	System	21 Aug 2020 01:32:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
Amendment Manager: User entered 'I'	(b) (4), (b) (6)	
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:32
	System	21 Aug 2020 01:32:29

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:53:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 08:26:56
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6) System	21 Aug 2020 01:32:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:26:55
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User coded data point as SOC: Investigations, HLGT: Hepatobiliary investigations, HLT: Liver function analyses, PT: Hepatic enzyme increased, LLT: Elevated liver enzymes - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:59:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Aug 2020 22:59:18
Data point term sent to Coder	System	17 Aug 2020 22:58:33
User entered 'ELEVATED LIVER ENZYMES'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:26:57
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:26:59
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:27:00
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 16:51:31
Query 'Per CDM: Response is required. Please provide.' answered with 'updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 16:27:38
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6)	15 Oct 2020 16:27:31
User opened query 'Per CDM: Response is required. Please provide.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 18:12:43
Amendment Manager inserted this DataPoint.	(b) (4), (b) (6)	
	System	21 Aug 2020 01:32:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:27:03
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '17 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:04
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:27:07
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:09
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:11
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 16:27:25
	(b) (4), (b) (6)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:48
reason for change: Data Entry Error	(b) (4)	
User entered 'Grade 4 (Grade 4)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:27:29
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	17 Aug 2020 22:58:48
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	17 Aug 2020 22:58:48
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	17 Aug 2020 22:58:32
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:30
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:27:32
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:27:35
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:37
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:40
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:46
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:48
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:27:51
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:53
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:55
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:57
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:27:59
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:28:01
	(b) (4), (b) (6)	
User entered 'None (NONE)'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:28:02
	(b) (4), (b) (6)	
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

US3022103

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:28:05
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:28:07
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:28:09
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:28:11
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:58:32
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:28:13
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:58:32

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered '0'	System	21 Aug 2020 01:32:32
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 01:32:32
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:53:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 01:32:29

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:42:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:46:57
User entered	(b) (4), (b) (6)	
'USA-US051-2020-mRNA-1273-P301000004'	System	15 Sep 2020 14:46:51
User entered 'New'	(b) (4), (b) (6)	15 Sep 2020 14:46:51
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	11 Nov 2020 01:37:33
	(b) (4), (b) (6)	
User closed query 'Per the source, AE term is spelled Epigastric. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:37:32
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Epigastric pain - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 21:46:38
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	09 Nov 2020 21:46:38
Data point term sent to Coder	System	09 Nov 2020 21:45:25
Query 'Per the source, AE term is spelled Epigastric. Please reconcile. ' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	09 Nov 2020 21:45:20
	(b) (4)	
Coding entries removed.	Shanice Bennett (b) (4)	09 Nov 2020 21:45:14
	(b) (4)	
User entered 'INTERMITTENT Epigastric PAIN' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Nov 2020 21:45:14
	(b) (4)	
User opened query 'Per the source, AE term is spelled Epigastric. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 18:00:36
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:34:13
	(b) (4), (b) (6)	
Query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly.' answered with 'unknown' (Site from Safety).	Shanice Bennett (b) (4)	22 Oct 2020 15:37:58
	(b) (4)	
User opened query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:40:36
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:06
	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly. ' answered with 'unknown' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:26:15
User opened query 'PV Query: Please provide the final diagnosis/etiology for the epigastric pain, and consider updating event term accordingly. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:36:35
Query 'PV Query: Please consider updating the event term to the final diagnosis or underlying reason for the intermittent epigastric pain.' canceled (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:36:14
User opened query 'PV Query: Please consider updating the event term to the final diagnosis or underlying reason for the intermittent epigastric pain.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:34:04
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Epigastric pain - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 19:21:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Sep 2020 19:21:52
Data point term sent to Coder	System	14 Sep 2020 16:50:56
User entered 'INTERMITTENT EIPGASTRIC PAIN'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:34:46
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	09 Nov 2020 20:34:49
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:34:54
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'PV query: Start date was reported as 16 Aug 2020 in EDC and in paper SAE form start date of the event was reported as 10 Sep 2020. Please confirm the start date and update EDC accordingly.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:36:07
Query 'PV query: Start date was reported as 16 Aug 2020 in EDC and in paper SAE form start date of the event was reported as 10 Sep 2020. Please confirm the start date and update EDC accordingly.' answered with 'chart states 16aug2020' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 22:34:03
User opened query 'PV query: Start date was reported as 16 Aug 2020 in EDC and in paper SAE form start date of the event was reported as 10 Sep 2020. Please confirm the start date and update EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:47:23
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:34:57
	(b) (4), (b) (6)	
User entered '16 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:00
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6) (b) (4), (b) (6)	30 Nov 2020 13:53:35
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	30 Nov 2020 13:53:35
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:05
	(b) (4), (b) (6)	
User closed query 'Per the source, the SAE was resolved on 21Aug2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6) (b) (4), (b) (6)	11 Nov 2020 01:37:41
Query 'Per the source, the SAE was resolved on 21Aug2020. Please reconcile.' answered with 'no sae isn't resolve, i have to contact patient' (Site from CRA).	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 21:45:36
User opened query 'Per the source, the SAE was resolved on 21Aug2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:00:37
	(b) (4), (b) (6)	
User closed query 'PV query: Please provide the end date of the event, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:10
Query 'PV query: Please provide the end date of the event, when available. Please do not respond to this query until the event has ended.' answered with 'yes' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	02 Oct 2020 21:26:19
User opened query 'PV query: Please provide the end date of the event, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:33:24
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 16:40:23
Query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 13:53:48
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 13:53:35
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 13:53:35
User opened query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 22:49:18
User closed query 'PV Query: Please confirm event stop date as paper SAE form has 14 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:35:52
Query 'PV Query: Please confirm event stop date as paper SAE form has 14 Sep 2020.' answered with 'this is ongoing per chart' (Site from Safety).	Shanice Bennett (b) (4)	19 Nov 2020 22:34:40
User opened query 'PV Query: Please confirm event stop date as paper SAE form has 14 Sep 2020.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:47:56
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:14
User closed query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:41:22
Query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' answered with 'update hen available ' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 21:45:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:46:01
User closed query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:34:22
Query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' answered with 'will update as applicable ' (Site from Safety).	Shanice Bennett (b) (4)	22 Oct 2020 15:38:07
User opened query 'PV query: Please provide the end date of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:37:23
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:18
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: As the event end date was in Nov 2020, did the subject receive the 2nd dosage of study medication? If yes, please provide the date. If no, please provide the rationale. ' canceled (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:33:00
User opened query 'PV Query: As the event end date was in Nov 2020, did the subject receive the 2nd dosage of study medication? If yes, please provide the date. If no, please provide the rationale. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:31:47
User entered empty.	System	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

Severity

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'PV Query: Severity was reported as Grade 2/moderate on the SAE paper form. In the EDC severity is denoted as Grade 4. Please confirm or update EDC as needed.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	21 Nov 2020 00:35:49
Query 'PV Query: Severity was reported as Grade 2/moderate on the SAE paper form. In the EDC severity is denoted as Grade 4. Please confirm or update EDC as needed.' answered with 'per chart grade 4' (Site from Safety).	Shanice Bennett (b) (4)	19 Nov 2020 22:34:51
User opened query 'PV Query: Severity was reported as Grade 2/moderate on the SAE paper form. In the EDC severity is denoted as Grade 4. Please confirm or update EDC as needed.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:48:05
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 01:37:47
User closed query 'Per the source, the severity was grade 4. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:37:45
Query 'Per the source, the severity was grade 4. Please reconcile. ' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	09 Nov 2020 21:45:51
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4)	09 Nov 2020 21:45:14
User opened query 'Per the source, the severity was grade 4. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:35:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:36:13
	(b) (4), (b) (6)	
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' canceled (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 16:42:01
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 16:41:38
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:29:29
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:29:31
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

US3022103

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:40:31
	(b) (4), (b) (6)	
User closed query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:34:33
Query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' answered with 'yes but nothing else is applicable to mark ' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	22 Oct 2020 15:36:50
User opened query 'PV Query: Please confirm if the subject was hospitalized overnight. If not, please reassess the reported seriousness criterion of hospitalization and determine if any other seriousness criteria were met (i.e. medically significant).' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Oct 2020 16:42:11
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:36:18
	(b) (4), (b) (6)	
User entered '16 Aug 2020'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	09 Nov 2020 20:36:21
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '17 Aug 2020'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:36:24
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:34
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 21:02:03
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:40:45
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:36
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:56
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:46
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:38
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:58
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:43
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:29:39
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:54
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 21:01:41
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:37:15
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per CDM, re-query: Adverse events starting after the first dose should have a "related" or "not related" selected for relationship to study procedure. Update as appropriate or clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 07:08:41
Query 'Per CDM, re-query: Adverse events starting after the first dose should have a "related" or "not related" selected for relationship to study procedure. Update as appropriate or clarify. ' answered with 'updated' (Site from DM).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:24:29
DataPoint Un-verified.	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:24:22
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 18:24:22
User opened query 'Per CDM, re-query: Adverse events starting after the first dose should have a "related" or "not related" selected for relationship to study procedure. Update as appropriate or clarify. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 18:25:40
User closed query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	20 Nov 2020 18:25:40
Query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' answered with 'due to stress' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 22:35:15
User opened query 'Per CDM: AE started after First Dose, however 'Relationship to Study Procedure' is 'Not Applicable'. Please review and update as appropriate. Thank you. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Nov 2020 12:34:46
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:37:40
User entered 'Not Applicable (NOT APPLICABLE)'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'PV Query: As second dose of the study medication was not given until >30 days after the first dose, please consider updating action taken to 'Dose Delayed'.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:09:22
Query 'PV Query: As second dose of the study medication was not given until >30 days after the first dose, please consider updating action taken to 'Dose Delayed'.' answered with 'DOSE NOT DELAYED DUE TO AE' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Dec 2020 14:44:28
User opened query 'PV Query: As second dose of the study medication was not given until >30 days after the first dose, please consider updating action taken to 'Dose Delayed'.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 13:57:07
User closed query 'PV query: Action taken with the study drug was reported as none in EDC. However, in paper SAE form it was reported as dose delayed , please confirm the action taken and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	21 Nov 2020 00:35:59
Query 'PV query: Action taken with the study drug was reported as none in EDC. However, in paper SAE form it was reported as dose delayed , please confirm the action taken and update accordingly.' answered with 'per chart this is correct' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 22:35:32
User opened query 'PV query: Action taken with the study drug was reported as none in EDC. However, in paper SAE form it was reported as dose delayed , please confirm the action taken and update accordingly.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 18:47:41
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:43
User closed query 'PV query: A 2nd dose of study drug was never administered. However, the action taken with study drug as updated to NONE. Please confirm if the study drug was withdrawn. If so, please update EDC with the appropriate action taken.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:41:32

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

Action taken with investigational product

Audit	User	Time (GMT)
Query 'PV query: A 2nd dose of study drug was never administered. However, the action taken with study drug as updated to NONE. Please confirm if the study drug was withdrawn. If so, please update EDC with the appropriate action taken.' answered with 'subject is awaiting answer on if she can receive 2nd dose or not' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 21:46:11
User opened query 'PV query: A 2nd dose of study drug was never administered. However, the action taken with study drug as updated to NONE. Please confirm if the study drug was withdrawn. If so, please update EDC with the appropriate action taken.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:41:02
User closed query 'PV query: Please confirm if the 2nd dose of study drug was administered. If not, please consider assessing action taken with study drug as withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:17
Query 'PV query: Please confirm if the 2nd dose of study drug was administered. If not, please consider assessing action taken with study drug as withdrawn. ' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:26:51
User entered 'None (NONE)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	02 Oct 2020 21:26:45
User opened query 'PV query: Please confirm if the 2nd dose of study drug was administered. If not, please consider assessing action taken with study drug as withdrawn. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:36:48
User entered 'Dose Delayed (DOSE DELAYED)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

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Generated On: 09 Jun 2021 14:53:37

None

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 18:54:29
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	12 Mar 2021 18:53:21
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:38:10
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	09 Oct 2020 16:37:31
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	02 Oct 2020 21:27:25
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	02 Oct 2020 21:27:20
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Sep 2020 11:16:14
User entered '1'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
User closed query 'Per CDM CLR Re-query: Per response , however there is no conmed recorded that matches this AE. Kindly review and amend as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	23 Mar 2021 12:53:57
Query 'Per CDM CLR Re-query: Per response , however there is no conmed recorded that matches this AE. Kindly review and amend as appropriate. ' answered with 'This is updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	19 Mar 2021 13:19:06
User opened query 'Per CDM CLR Re-query: Per response , however there is no conmed recorded that matches this AE. Kindly review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:33:27
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 01:33:27
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Con meds are present ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	16 Mar 2021 14:59:38
User entered '1' reason for change: Data Entry Error	Chevon Roberts (b) (4)	12 Mar 2021 18:54:29
DataPoint Un-verified.	(b) (4) Chevon Roberts (b) (4)	12 Mar 2021 18:53:21
Signature has been broken.	(b) (4) Chevon Roberts (b) (4)	12 Mar 2021 18:53:21
User entered '0' reason for change: Data Entry Error	(b) (4) Chevon Roberts (b) (4)	12 Mar 2021 18:53:21

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4), (b) (6) (b) (4), (b) (6)	(b) (4), (b) (6) 10 Mar 2021 11:39:15
DataPoint Verified.	Paul Bradley (b) (4) (b) (4) (b) (4), (b) (6)	23 Feb 2021 16:55:32 09 Nov 2020 20:38:12
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	02 Oct 2020 21:27:20
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
User entered '1' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	16 Mar 2021 14:59:16
User closed query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	12 Mar 2021 01:08:55
Query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field. ' answered with 'Updated' (Site from DM).	Chevon Roberts (b) (4) (b) (4)	08 Mar 2021 19:13:44
Signature has been broken.	Chevon Roberts (b) (4) (b) (4)	08 Mar 2021 19:13:36
User entered '0' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4) (b) (4), (b) (6)	08 Mar 2021 19:13:36
User opened query 'Per DM CLR: Other action taken = Concomitant Procedure. Please disregard query in Con procedure, please note that Diagnostic procedures are not considered treatment. Please review and add therapeutic procedure as appropriate or update Treatment Required field. ' (Site from DM).		08 Mar 2021 03:07:28
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	05 Mar 2021 22:57:44
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 20:02:26
Signature has been broken.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 20:02:26
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 20:02:26
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	09 Nov 2020 21:01:16

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User entered '0'	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4)	01 Dec 2020 16:40:27
Query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 13:53:53
DataPoint Un-verified.	(b) (4), (b) (6)	30 Nov 2020 13:53:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 13:53:35
User opened query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 22:49:33
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:29:56
User closed query 'Per the source, the event was resolved 21Aug2020. Please review.' (Site from CRA).	(b) (4), (b) (6)	11 Nov 2020 01:37:57
User closed query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:41:46
Query 'Per the source, the event was resolved 21Aug2020. Please review.' answered with 'updated' (Site from CRA).	Shanice Bennett (b) (4)	09 Nov 2020 21:46:22
Query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' answered with 'correct' (Site from Safety).	Shanice Bennett (b) (4)	09 Nov 2020 21:46:18
User opened query 'Per the source, the event was resolved 21Aug2020. Please review.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:39:19

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:46:24
User closed query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:35:05
Query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' answered with 'will update as applicable ' (Site from Safety).	Shanice Bennett (b) (4)	22 Oct 2020 15:37:47
User opened query 'PV query: Please provide the final outcome of the event, when available. Please leave query open until information is received.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:39:36
User closed query 'PV query: Please provide the final outcome of the event, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:21
Query 'PV query: Please provide the final outcome of the event, when available. Please do not respond to this query until the event has ended.' answered with 'not resolved ' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:27:36
User opened query 'PV query: Please provide the final outcome of the event, when available. Please do not respond to this query until the event has ended.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:33:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:31:51
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	09 Nov 2020 20:39:24
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:39:22
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'PV Query: As the event end date was in Nov 2020, did the subject receive the 2nd dosage of study medication? If yes, please provide the date. If no, please provide the rationale. ' (Site from Safety).	(b) (4) (b) (4), (b) (6)	09 Dec 2020 18:34:28
Query 'PV Query: As the event end date was in Nov 2020, did the subject receive the 2nd dosage of study medication? If yes, please provide the date. If no, please provide the rationale. ' answered with 'yes visit 2 was performed' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 19:34:53
User opened query 'PV Query: As the event end date was in Nov 2020, did the subject receive the 2nd dosage of study medication? If yes, please provide the date. If no, please provide the rationale. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 15:33:14
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:32:21
	(b) (4), (b) (6)	
User closed query 'PV query: Please provide a redacted discharge summary when available.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 22:42:07
Query 'PV query: Please provide a redacted discharge summary when available.' answered with 'Will send medical records. ' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 21:46:53
User opened query 'PV query: Please provide a redacted discharge summary when available.' (Site from Safety).	(b) (4), (b) (6)	30 Oct 2020 12:46:53
User closed query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 20:35:10
Query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such.' answered with 'unknown ' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	22 Oct 2020 15:37:36

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such.' (Site from Safety).	(b) (4), (b) (6)	12 Oct 2020 16:40:02
User closed query 'PV Query: Please report if the patient had a COVID test while hospitalized. If yes, please provide result and date.' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:26
User closed query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such. ' (Site from Safety).	(b) (4), (b) (6)	05 Oct 2020 12:54:24
Query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such. ' answered with 'pending records' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:27:50
Query 'PV Query: Please report if the patient had a COVID test while hospitalized. If yes, please provide result and date.' answered with 'no' (Site from Safety).	Shanice Bennett (b) (4)	02 Oct 2020 21:27:45
User opened query 'PV Query: Please report if the patient had a COVID test while hospitalized. If yes, please provide result and date.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:34:22
User opened query 'PV Query: Please assess if the pericardial effusion at the base of the heart met AE/ SAE reporting criteria. If so please report. If not please state as such. ' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 19:32:47
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:51:15
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	14 Sep 2020 16:51:15
User entered 'PENDING MEDICAL RECORDS.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	14 Sep 2020 16:51:15
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	14 Sep 2020 16:50:30
User entered empty.	Shanice Bennett (b) (4)	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	14 Sep 2020 16:50:30

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:53:37

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	14 Sep 2020 16:50:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	(b) (4), (b) (6) 03 May 2021 06:03:29
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:32:38
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:10:11

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:33:28
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: CORTICOSTEROIDS, PRODUCT: FLUTICASONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 21:13:12
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Jul 2020 21:13:12
	(b) (4)	
Data point term sent to Coder	System	31 Jul 2020 21:12:02
User entered 'Fluticasone'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:30
	(b) (4), (b) (6)	
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:33
	(b) (4), (b) (6)	
User entered 'seasonal allergies'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:35
	(b) (4), (b) (6)	
User entered '50'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:37
	(b) (4), (b) (6)	
User entered 'ug (ug)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:38
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:41
	(b) (4), (b) (6)	
User entered 'twice daily (BID)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:43
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:45
	(b) (4), (b) (6)	
User entered 'Nasal (NASAL)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:49
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:33:51
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:07:19
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stella Yoon (b) (4)	31 Jul 2020 21:11:50
answered with 'ongoing' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 21:11:01
User entered 'un UNK 2003'	Stella Yoon (b) (4)	31 Jul 2020 21:11:01
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:53
	(b) (4), (b) (6)	
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:55
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:33:58
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:00
	(b) (4), (b) (6)	
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:01

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	31 Jul 2020 21:11:01

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 21:11:01

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 21:11:01

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:34:17
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 05:35:41
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 05:35:41
Data point term sent to Coder	System	31 Aug 2020 15:03:23
User entered 'ketoconazole' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:03:13
Coding entries removed.	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:02:44
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: IMIDAZOLE AND TRIAZOLE DERIVATIVES, PRODUCT: KETOCONAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 11:25:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Aug 2020 11:25:05
Data point term sent to Coder	System	31 Jul 2020 21:12:02
User entered 'ketoconazole'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:19
	(b) (4), (b) (6)	
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:20
	(b) (4), (b) (6)	
User closed query ""Per DM CLR: Please update the indication to reflect the location/type of OTOMYCOSIS (right, left or bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 06:28:33
' (Site from DM).		
Query ""Per DM CLR: Please update the indication to reflect the location/type of OTOMYCOSIS (right, left or bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:03:18
' answered with 'updated' (Site from DM).		
User entered 'ONYCHOMYCOSIS bilateral' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:02:44
User opened query ""Per DM CLR: Please update the indication to reflect the location/type of OTOMYCOSIS (right, left or bilateral). Please reconcile with the AE and Med History eCRFs as appropriate.	(b) (4), (b) (6)	31 Aug 2020 13:58:24
' (Site from DM).		
User entered 'otomycosis'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:22
	(b) (4), (b) (6)	
User closed query ' Per DM CLR: Please note, 15 g pertains to drug tube weight. So please verify if the DOSE to reflect the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = applications) would be more appropriate recording. Update eCRF as appropriate." ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 06:30:04
Query ' Per DM CLR: Please note, 15 g pertains to drug tube weight. So please verify if the DOSE to reflect the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = applications) would be more appropriate recording. Update eCRF as appropriate." ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:03:24
User entered '200-400' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:03:13
User opened query ' Per DM CLR: Please note, 15 g pertains to drug tube weight. So please verify if the DOSE to reflect the single dose taken by the subject in # of applications (e.g., Dose=1, If dose unit is Other, specify = applications) would be more appropriate recording. Update eCRF as appropriate." ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:58:32
User entered '15'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:29
	(b) (4), (b) (6)	
User entered 'mg (mg)' reason for change: Data Entry Error	Stella Yoon (b) (4) (b) (4)	31 Aug 2020 15:03:13
User entered 'g (g)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:41
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:45
	(b) (4), (b) (6)	
User entered 'once daily (QD)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:50
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:51
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: The dose provided does not correspond to a TOPICAL formulation of this medication. Please verify if "Oral" is a more appropriate recording. Update eCRF as appropriate. Otherwise, provide clarification in query response.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	09 Oct 2020 16:37:04
Query 'Per DM CLR: The dose provided does not correspond to a TOPICAL formulation of this medication. Please verify if "Oral" is a more appropriate recording. Update eCRF as appropriate. Otherwise, provide clarification in query response.' answered with 'this is correct' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Oct 2020 20:30:29
User opened query 'Per DM CLR: The dose provided does not correspond to a TOPICAL formulation of this medication. Please verify if "Oral" is a more appropriate recording. Update eCRF as appropriate. Otherwise, provide clarification in query response.' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 05:28:00
User entered 'Topical (TOPICAL)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:53
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:34:55
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	03 Aug 2020 13:07:23
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	Stella Yoon (b) (4)	31 Jul 2020 21:11:45
answered with 'ongoing' (Site from System).	(b) (4)	
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	31 Jul 2020 21:11:37
User entered 'un UNK 2018'	Stella Yoon (b) (4)	31 Jul 2020 21:11:37
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:34:58
	(b) (4), (b) (6)	
User entered '0'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:00
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:02
	(b) (4), (b) (6)	
User entered empty.	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:04
	(b) (4), (b) (6)	
User entered 'No (N)'	Stella Yoon (b) (4) (b) (4)	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	31 Jul 2020 21:11:37

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 11:12:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 11:12:30
Data point term sent to Coder	System	18 Mar 2021 14:45:18
Coding entries removed.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 14:44:21
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:15
	(b) (4), (b) (6)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: SUCRALFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:05:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:05:15
Data point term sent to Coder	System	17 Aug 2020 22:54:29
User entered 'SUCRALFATE'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 14:44:21
Signature has been broken.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 14:44:21
User entered 'Epigastric Pain' reason for change:	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 14:44:21
Data Entry Error	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:35:21
	(b) (4), (b) (6)	
User entered 'ABDOMINAL PAIN'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:35:24
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'l'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
	(b) (4)	
User entered 'g (g)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:35:32
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:35:36
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:35:38
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:35:40
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User closed query 'Per the source, the start date was 16Aug2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:19:25
Query 'Per the source, the start date was 16Aug2020. Please reconcile.' answered with 'updated date' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:19:23
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 23:32:12
User entered '16 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:31:16
DataPoint Verified.	(b) (4), (b) (6)	13 Nov 2020 23:31:16
	(b) (4), (b) (6)	12 Nov 2020 16:35:48
	(b) (4), (b) (6)	
User opened query 'Per the source, the start date was 16Aug2020. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:31:38
	(b) (4), (b) (6)	
User entered '17 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:35:50
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Jan 2021 13:51:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	08 Jan 2021 19:35:10
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 19:35:06
User closed query 'Re-query: Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	08 Jan 2021 09:55:55
Query 'Re-query: Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' answered with 'per chart this is still ongoing' (Site from CRA).	(b) (4), (b) (6)	
User opened query 'Re-query: Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 02:12:47
User closed query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	Shanice Bennett (b) (4)	19 Nov 2020 22:36:03
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
Query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:19:59
DataPoint Un-verified.	(b) (4), (b) (6)	16 Nov 2020 02:19:59
	(b) (4), (b) (6)	13 Nov 2020 23:33:12
	(b) (4), (b) (6)	13 Nov 2020 23:32:19
	(b) (4), (b) (6)	13 Nov 2020 23:31:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:31:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:35:58
	(b) (4), (b) (6)	
User opened query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:31:02
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Jan 2021 19:35:06
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:33:12
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 23:31:16
User entered '21 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:31:16
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:01
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:36:03
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:53:34
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User entered '1'	System	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User entered '1'	System	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:45:19
User entered '804 (804)'	System	17 Aug 2020 22:53:34

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:48:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 09:48:34
Data point term sent to Coder	System	18 Mar 2021 14:45:18
Coding entries removed.	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 14:44:40
User signature succeeded.	Paul Bradley (b) (4) (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:18
	(b) (4), (b) (6)	
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:22:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Aug 2020 07:22:21
Data point term sent to Coder	System	17 Aug 2020 22:54:30
User entered 'PANTOPRAZOLE'	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	18 Mar 2021 14:44:40
Signature has been broken.	(b) (4), (b) (6) (b) (4), (b) (6)	18 Mar 2021 14:44:40
User entered 'Epigastric Pain' reason for change:	(b) (4), (b) (6)	18 Mar 2021 14:44:40
Data Entry Error	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:36:21
	(b) (4), (b) (6)	
User entered 'ABDOMINAL PAIN'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered '40'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered 'mg (mg)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) Shanice Bennett (b) (4)	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:36:34
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:36:36
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	16 Nov 2020 02:20:16
User closed query 'Per the source, the start date was 16Aug2020. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:20:15
Query 'Per the source, the start date was 16Aug2020. Please reconcile. ' answered with 'updated ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:33:49
DataPoint Un-verified.	(b) (4), (b) (6)	13 Nov 2020 23:33:37
User entered '16 Aug 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	13 Nov 2020 23:33:37
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:37
	(b) (4), (b) (6)	
User opened query 'Per the source, the start date was 16Aug2020. Please reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:24:27
	(b) (4), (b) (6)	
User entered '17 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:36:39
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	15 Jan 2021 13:51:22
DataPoint Un-verified.	(b) (4), (b) (6) (b) (4), (b) (6)	08 Jan 2021 19:35:26
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6)	08 Jan 2021 19:35:21
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 09:55:47
User closed query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	16 Nov 2020 02:20:39
Query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' answered with 'still ongoing' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:33:57
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:41
User opened query 'Per the source, the SAE has an end date of 21Aug2020. Please confirm if medication is ongoing.' (Site from CRA).	(b) (4), (b) (6)	09 Nov 2020 20:29:30
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Jan 2021 19:35:21
User entered '09 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Jan 2021 19:35:21
DataPoint Verified.	(b) (4), (b) (6)	12 Nov 2020 16:36:44
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4) (b) (4)	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:36:46
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:54:13
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User entered '1'	System	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User entered '1'	System	17 Aug 2020 22:54:13

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:51
User entered '804 (804)'	System	17 Aug 2020 22:54:13

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:36:53
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	17 Aug 2020 22:56:15
User coded data point as Term Coded data point by	(b) (4)	17 Aug 2020 22:56:15
User: Coder System - version		
WHODrug-Global-B3\202003.		
Data point term sent to Coder	System	17 Aug 2020 22:55:31
User entered 'ADVIL'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:36:57
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Concomitant Medication' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	01 Sep 2020 10:57:15
Query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Concomitant Medication' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' answered with 'updated' (Site from DM).	Stella Yoon (b) (4)	31 Aug 2020 15:04:15
User opened query 'Per DM CLR: The corresponding AE recorded (AE# 1) does not show 'Concomitant Medication' =Yes. Please reconcile and update applicable eCRFs as appropriate. ' (Site from DM).	(b) (4), (b) (6)	31 Aug 2020 13:58:55
User entered 'NECK PAIN'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:36:59
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '400'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:37:01
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'mg (mg)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:37:03
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered 'three times daily (TID)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:37:15
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:37:17
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:37:19
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '15 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:37:21
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:37:24
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered '16 Aug 2020'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	12 Nov 2020 16:37:25
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	17 Aug 2020 22:55:14
	(b) (4)	

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User entered '3'	System	17 Aug 2020 22:55:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User entered '1'	System	17 Aug 2020 22:55:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 09:21:16
User entered '804 (804)'	System	17 Aug 2020 22:55:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	02 Dec 2020 14:53:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Dec 2020 14:53:30
Data point term sent to Coder	System	02 Dec 2020 14:51:51
User entered 'Tylenol'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	15 Jan 2021 16:08:54
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' answered with 'headache did not meet ae criteria ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 19:34:18

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:06:32
User entered 'headache'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '500'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '0'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '24 Nov 2020'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

Was this medication taken for solicited event?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User closed query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	15 Jan 2021 16:08:51
Query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' answered with 'updated' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 19:34:22
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	13 Jan 2021 19:34:05
User opened query 'Per DM CLR: Was this medication taken for solicited event?=NO. However, there is a record of this event in Diary within 7-day reporting of SAR. Review if this should be updated. Else, provide clarification on query response.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 05:06:43
User entered 'No (N)'	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User entered '2'	System	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User entered '1'	System	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:53:37

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:19:54
User entered '804 (804)'	System	02 Dec 2020 14:51:14

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:53:37

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	03 May 2021 06:03:29
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:31:02
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	17 Sep 2020 16:39:50

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:37

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '15 Sep 2020'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:31:28

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'MRI of the abdomen'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:31:28

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:31:28

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:53:37

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:31:28

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:37

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '16 Aug 2020'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:32:02

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:37

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'CT abdomen pelvis with contrast'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:32:02

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:37

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:48
User closed query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	02 Mar 2021 13:17:27
Query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Mar 2021 20:03:03
User opened query 'Per DM CLR: Indication = Adverse Event, however, the corresponding AE's Other Action Taken does not include 'Concomitant Procedure'. Please reconcile and update necessary eCRF fields, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Feb 2021 14:07:08
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:32:02

US3022103

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:53:37

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:30:48
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered empty.	(b) (4) (b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 14:32:02

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '15/Sep/2020 10:48'	(b) (4) System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:54:35
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	15 Sep 2020 14:48:03
	(b) (4), (b) (6)	

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '05/Oct/2020 08:54'	(b) (4) System	05 Oct 2020 12:54:42

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
Reviewed for Safety.	(b) (4), (b) (6)	23 Oct 2020 20:35:18
User entered 'I'	(b) (4), (b) (6)	05 Oct 2020 12:54:42
	(b) (4), (b) (6)	

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '23/Oct/2020 20:35'	(b) (4) System	23 Oct 2020 20:35:29

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:38:05
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	23 Oct 2020 20:35:29

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '10/Nov/2020 17:29'	(b) (4) System	10 Nov 2020 22:29:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 12:38:05
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 22:29:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '24/Nov/2020 07:38'	(b) (4) System	24 Nov 2020 12:38:14

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
Reviewed for Safety.	(b) (4)	01 Dec 2020 16:40:34
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 12:38:14

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '01/Dec/2020 16:41'	(b) (4) System	01 Dec 2020 16:41:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
Reviewed for Safety.	(b) (4), (b) (6)	09 Dec 2020 21:19:05
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 16:41:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '09/Dec/2020 21:19'	(b) (4) System	09 Dec 2020 21:19:15

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	16 Dec 2020 21:11:52
User entered 'I'	(b) (4), (b) (6)	09 Dec 2020 21:19:15

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Oct 2020 12:54:35
	(b) (4), (b) (6)	
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered '16/Dec/2020 16:12'	(b) (4) System	16 Dec 2020 21:12:07

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	02 Mar 2021 14:45:06
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
User entered 'I'	(b) (4) (b) (4), (b) (6)	16 Dec 2020 21:12:07

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:57:44
User entered '02/Mar/2021 09:45'	(b) (4) System	02 Mar 2021 14:45:15

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 17:29:56
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 22:57:44
User entered 'I'	(b) (4), (b) (6)	02 Mar 2021 14:45:15

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	12 Nov 2020 16:14:29
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
User entered '09/Mar/2021 12:31'	(b) (4) System	09 Mar 2021 17:31:39

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
Reviewed for Safety.	(b) (4)	17 Mar 2021 13:46:00
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 17:31:39

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Site Address: [State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
User entered '15/Mar/2021 11:21'	(b) (4) System	15 Mar 2021 15:21:23

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
Reviewed for Safety.	(b) (4)	17 Mar 2021 13:46:00
User entered 'I'	(b) (4), (b) (6)	15 Mar 2021 15:21:23

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:29
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered	(b) (4), (b) (6)	
'USA-US051-2020-MRNA-1273-P301000004'	System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:31
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:34
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:22
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Yes (Y)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:36
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:41
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Nov 2020 16:14:42
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'No (N)'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

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Form: Safety Report Form

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[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:15
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Paul'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:13
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Bradley'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:11
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '340 Eisenhower Dr.'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:09
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'Savannah'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:07
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered 'GA'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:05
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Sep 2020 14:47:39
User entered '31406'	(b) (4), (b) (6) System	15 Sep 2020 14:46:51

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

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[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 21:10:01
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Oct 2020 12:54:35
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:12:20
User entered 'US' (non-conformant).	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form

Generated On: 09 Jun 2021 14:53:37

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '12'	System	17 Mar 2021 13:45:56
User entered '11'	System	15 Mar 2021 15:21:23
User entered '10'	System	09 Mar 2021 17:31:39
User entered '9'	System	02 Mar 2021 14:45:15
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 16:55:32
	(b) (4)	
User entered '8'	System	16 Dec 2020 21:12:07
User entered '7'	System	09 Dec 2020 21:19:15
User entered '6'	System	01 Dec 2020 16:41:03
User entered '5'	System	24 Nov 2020 12:38:14
User entered '4'	System	10 Nov 2020 22:29:03
User entered '3'	System	23 Oct 2020 20:35:29
User entered '2'	System	05 Oct 2020 12:54:42
User entered '1'	System	15 Sep 2020 14:48:03

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 14:53:37

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
User entered '17/Mar/2021 09:45'	(b) (4) System	17 Mar 2021 13:45:56

US3022103

Folder: SAE USA-US051-2020-MRNA-1273-P301000004

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 14:53:37

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:17:35
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:03:03
Reviewed for Safety.	(b) (4)	17 Mar 2021 13:46:00
User entered 'I'	(b) (4), (b) (6)	17 Mar 2021 13:45:56