

US3022186 (Prod: Meridian Clinical Research-Savannah)

Generated By: KC Joubran

Generated On: 09 Jun 2021 14:47:56

All time stamps listed in this document are displayed in GMT

US3022186

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 18:15:12

Generated On: 09 Jun 2021 14:47:56

Participant ID

US3022186

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

US3022186

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Date of Birth (MMM yyyy)	(b) (6) 1954
Age	66
Age Units	YEARS
Age (Derived)	66
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 18:17:01

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Date of Informed Consent (<i>dd MMM yyyy</i>)	20 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input type="radio"/>
	Amendment 2 <input checked="" type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 18:17:01

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 18:17:01

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Condition	ANXIETY
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 18:17:01

Generated On: 09 Jun 2021 14:47:56

Condition	LEFT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN NOV 2017
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN NOV 2017
Stop date completely unknown	False
Start Month and Year (derived)	NOV 2017
Start Year (derived)	2017
Stop Month and Year (derived)	NOV 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Condition	RIGHT KNEE REPLACEMENT
Start date (dd MMM yyyy)	UN DEC 2018
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN DEC 2018
Stop date completely unknown	False
Start Month and Year (derived)	DEC 2018
Start Year (derived)	2018
Stop Month and Year (derived)	DEC 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Condition	WASP ALLERGY
Start date (dd MMM yyyy)	UN UNK 2000
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Condition	LEFT KNEE OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Condition	RIGHT KNEE OSTEOARTHRITIS
Start date (dd MMM yyyy)	UN UNK 1976
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2018
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1976
Start Year (derived)	1976
Stop Month and Year (derived)	JAN 2018
Stop Year (derived)	2018

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Condition	CHRONIC DIARRHEA
Start date (dd MMM yyyy)	UN UNK 2019
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	20 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	09:47 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 09:47
Height (<i>xxx.x</i>)	170.1 cm
Weight (<i>xxx.x</i>)	70.2 kg
BMI (<i>xxx.x</i>)	24.26211 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:17:01

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:17:01

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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

PAINTING CONTRACTOR

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 18:17:01

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	20 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

What was the date of randomization? (dd MMM yyyy) 20 AUG 2020

What was the participant's randomization number? 187100

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

Human Immunodeficiency Virus (HIV) infection Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

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)	20 AUG 2020
Time of assessment (00:00-23:59)	09:47 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 09:47
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	144 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	90 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Height	ND - Not Done
Weight	ND - Not Done
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)	20 AUG 2020
Time of assessment (00:00-23:59)	10:58 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:58
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

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) 20 AUG 2020

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

Treatment Date and Time (derived) 20 AUG 2020 10:26

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	09:58 (24 HR)
Collection date and time (derived)	20 AUG 2020 09:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:09	20 AUG 2020 10:09
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

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 14:47:56

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

20 AUG 2020 11:01

PC Open Date & Time

20 AUG 2020 10:46

PC Close Date & Time

20 AUG 2020 13:16

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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 97.2 °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	20 AUG 2020 19:57
PC Open Date & Time	20 AUG 2020 14:11
PC Close Date & Time	21 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °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

21 AUG 2020 20:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 19:46

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

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

23 AUG 2020 19:23

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

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

24 AUG 2020 19:00

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

97.2 °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

25 AUG 2020 20:11

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 17:49

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

20 AUG 2020 11:02

PC Open Date & Time

20 AUG 2020 10:46

PC Close Date & Time

20 AUG 2020 13:16

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

20 AUG 2020 19:57

PC Open Date & Time

20 AUG 2020 14:11

PC Close Date & Time

21 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

21 AUG 2020 20:01

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

22 AUG 2020 19:47

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

23 AUG 2020 19:23

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

24 AUG 2020 19:01

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

25 AUG 2020 20:12

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

26 AUG 2020 17:49

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 11:03
PC Open Date & Time	20 AUG 2020 10:46
PC Close Date & Time	20 AUG 2020 13:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 19:58
PC Open Date & Time	20 AUG 2020 14:11
PC Close Date & Time	21 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

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 ☒

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 20:03
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 19:48
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

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 ☒

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

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 ☒

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:02
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 20:13
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

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 ☒

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 17:50
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3022186

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:15:15

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:15:15

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:15:15

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:15:15

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 18:17:02

Generated On: 09 Jun 2021 14:47:56

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)	24 SEP 2020
Time of assessment (00:00-23:59)	11:28 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 11:28
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 18:17:02

Generated On: 09 Jun 2021 14:47:56

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)	24 SEP 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	24 SEP 2020 12:32
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)	59 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3022186

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

24 SEP 2020

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

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

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) 24 SEP 2020

What was the treatment time? (00:00-23:59) 12:01 (24 HR)

Treatment Date and Time (derived) 24 SEP 2020 12:01

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

US3022186

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

24 SEP 2020

Collection time (00:00-23:59)

11:38 (24 HR)

Collection date and time (derived)

24 SEP 2020 11:38

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Collection date (dd MMM yyyy)			24 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:41	24 SEP 2020 11:41
Nasopharyngeal Swab 2	No		

US3022186

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

24 SEP 2020 12:33

PC Open Date & Time

24 SEP 2020 12:21

PC Close Date & Time

24 SEP 2020 14:51

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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 98.4 °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	24 SEP 2020 18:17
PC Open Date & Time	24 SEP 2020 15:46
PC Close Date & Time	25 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °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

25 SEP 2020 18:08

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

96.4 °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

26 SEP 2020 15:21

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

27 SEP 2020 18:14

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 16:58

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

96.7 °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

29 SEP 2020 23:06

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 SEP 2020 18:15

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 SEP 2020 12:34

PC Open Date & Time

24 SEP 2020 12:21

PC Close Date & Time

24 SEP 2020 14:51

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

24 SEP 2020 18:18

PC Open Date & Time

24 SEP 2020 15:46

PC Close Date & Time

25 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

25 SEP 2020 18:09

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

26 SEP 2020 15:22

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

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 SEP 2020 18:14

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

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 SEP 2020 16:58

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

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 SEP 2020 23:07

PC Open Date & Time

29 SEP 2020 12:00

PC Close Date & Time

30 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

30 SEP 2020 18:16

PC Open Date & Time

30 SEP 2020 12:00

PC Close Date & Time

01 OCT 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 12:35
PC Open Date & Time	24 SEP 2020 12:21
PC Close Date & Time	24 SEP 2020 14:51

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

No ☒

Yes ☐

PC Time stamp	24 SEP 2020 18:19
PC Open Date & Time	24 SEP 2020 15:46
PC Close Date & Time	25 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

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 ☒

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 18:09
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

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 ☒

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 15:23
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

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 ☒

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EAB) (1725)

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	27 SEP 2020 18:15
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

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 ☒

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 16:59
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 23:07
PC Open Date & Time	29 SEP 2020 12:00
PC Close Date & Time	30 SEP 2020 11:59

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

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 ☒

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

Yes <input type="checkbox"/>	
PC Time stamp	30 SEP 2020 18:16
PC Open Date & Time	30 SEP 2020 12:00
PC Close Date & Time	01 OCT 2020 11:59

US3022186

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

01 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

08 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 18:17:02

Generated On: 09 Jun 2021 14:47:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 18:17:02

Generated On: 09 Jun 2021 14:47:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	26 OCT 2020
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	26 OCT 2020 11:05
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022186

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 18:17:02

Generated On: 09 Jun 2021 14:47:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 OCT 2020

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

US3022186

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 18:17:02

Generated On: 09 Jun 2021 14:47:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 OCT 2020

Collection time (00:00-23:59)

11:17 (24 HR)

Collection date and time (derived)

26 OCT 2020 11:17

US3022186

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:17:02

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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	22 OCT 2020 12:04:19
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 15:40:37

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

07 NOV 2020 12:00:29

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	25 NOV 2020 12:13:12
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 12:34:00

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 110

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 DEC 2020 12:40:38

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

14 DEC 2020 12:03:19

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

21 DEC 2020 12:03:31

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 10:19:07

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

02 JAN 2021 00:29:39

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

10 JAN 2021 16:58:50

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

18 JAN 2021 16:00:53

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

23 JAN 2021 04:56:55

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

30 JAN 2021 15:37:14

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

09 FEB 2021 18:58:03

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 FEB 2021 18:05:52

Patient Cloud Open Date & Time

13 FEB 2021 00:01

Patient Cloud Close Date & Time

17 FEB 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 FEB 2021 00:01

[Patient Cloud Close Date & Time](#)

24 FEB 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

03 MAR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

09 MAR 2021 12:46:55

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

15 MAR 2021 17:13:30

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

20 MAR 2021 11:52:04

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

27 MAR 2021 09:30:46

Patient Cloud Open Date & Time

27 MAR 2021 00:01

Patient Cloud Close Date & Time

31 MAR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

03 APR 2021 16:07:42

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

13 APR 2021 18:05:49

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

19 APR 2021 12:01:12

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

24 APR 2021 17:47:26

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

03 MAY 2021 12:12:35

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 271

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 292

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT	DAY 320
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 341

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

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

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

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

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 397

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

22 SEP 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 2021 00:01
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Patient Cloud Close Date & Time	06 OCT 2021 23:59
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US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 432

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐ Yes ☐

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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°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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

29 DEC 2021 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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°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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

20 APR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT	DAY 621
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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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.

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

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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.

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

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25 MAY 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Open Date & Time](#)

09 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2022 00:01
Patient Cloud Close Date & Time	20 JUL 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 719

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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°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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

19 OCT 2022 23:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

DAY 796

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

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

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

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

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

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

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 ☐

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2022 23:59

US3022186

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 14:47:56

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		09 MAR 2021 12:38:22

US3022186

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:17:01

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:15:15

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:15:15

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 18:15:15

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 18:15:15

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 24 Feb 2021 00:08:30

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 24 Feb 2021 00:08:30

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	09 MAR 2021
Time of assessment (<i>00:00-23:59</i>)	11:05 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 11:05
Temperature (<i>xxx.x</i>)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	87 beats/min
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3022186

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	09 MAR 2021
Collection time (00:00-23:59)	11:24 (24 HR)
Collection date and time (derived)	09 MAR 2021 11:24

US3022186

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022186

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 14:47:56

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"/>

US3022186

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 14:47:56

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3022186

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

Form: Visit Date

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	09 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3022186

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

Form: Unblinding

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Date of updated informed consent (<i>dd MMM yyyy</i>)	13 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Under what version of the Protocol was the Participant unblinded?	Amendment 5 <input type="radio"/> Amendment 6 or later <input checked="" type="radio"/>
Date of unblinding (<i>dd MMM yyyy</i>)	13 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3022186

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

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

US3022186

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	11:05 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 11:05
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)	87 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3022186

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	09 MAR 2021
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	09 MAR 2021 12:32
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)	77 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	133 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	88 mmHg
Diastolic Blood Pressure units	MMHG

US3022186

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

Form: Physical Examination

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

09 MAR 2021

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

US3022186

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

Form: Exposure

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 09 MAR 2021

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

Treatment Date and Time (derived) 09 MAR 2021 12:00

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

US3022186

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

09 MAR 2021

Collection time (00:00-23:59)

11:24 (24 HR)

Collection date and time (derived)

09 MAR 2021 11:24

US3022186

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 23:00:00

Generated On: 09 Jun 2021 14:47:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 JAN 2021
Collection time (00:00 - 23:59)	13:55
Collection Date and Time (derived)	13 JAN 2021 13:55

US3022186

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

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	19 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 APR 2021
Time of assessment (00:00-23:59)	11:08 (24 HR)
Vital Signs Date and Time (derived)	19 APR 2021 11:08
Temperature (xxx.x)	37.1 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	82 mmHg
Diastolic Blood Pressure units	MMHG

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	19 APR 2021
Time of assessment (00:00-23:59)	12:19 (24 HR)
Vital Signs Date and Time (derived)	19 APR 2021 12:19
Temperature (xxx.x)	37.0 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3022186

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 APR 2021

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

US3022186

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 19 APR 2021

What was the treatment time? (00:00-23:59) 11:38 (24 HR)

Treatment Date and Time (derived) 19 APR 2021 11:38

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

US3022186

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3022186

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

Was Contact Attempted? Yes ☐
No ☐

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

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

Comments

If Contact Not Made, please provide Comments

US3022186

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3022186

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 18:15:12

Generated On: 09 Jun 2021 14:47:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

AEID	USA-US051-2020-MRNA-1273-P30 1000009
Adverse event	SYNCOPE
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)	11 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	11 OCT 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)	11 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	14 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT REPORTED HAVING FALLEN TWICE AND WENT TO THE EMERGENCY DEPARTMENT IN STATESBORO. HE WAS INFORMED THAT HE WAS DEHYDRATED AND THAT'S WHY HE FAINTED AND FELL.
Serious Adverse Event Derived (CSA Programming Field Only)	1

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

AEID	USA-US051-2020-MRNA-1273-P30 1000009
Adverse event	FRACTURE RIBS
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)	11 OCT 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 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)	11 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	14 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

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

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

AEID	USA-US051-2020-MRNA-1273-P30 1000009
Adverse event	DEHYDRATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 OCT 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)	11 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	14 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

AEID	USA-US051-2020-MRNA-1273-P30 1000012
Adverse event	DEHYDRATION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 NOV 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)	13 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)	11 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

AEID	USA-US051-2020-MRNA-1273-P30 1000012
Adverse event	DIARRHEA
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)	11 NOV 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)	13 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)	11 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	13 NOV 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

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

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

AEID	
Adverse event	LYMPHOCYTIS COLITIS
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 DEC 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 checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
Persistent or significant disability or incapacity	False

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

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	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

AEID	USA-US051-2021-MRNA-1273-P30 1000006
Adverse event	NON- SMALL CELL CARCINOMA OF THE LUNG
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	14 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	14 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	25 JAN 2021
Admitted to ICU?	Yes <input checked="" 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 (8)

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

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

HE HAD A PLANNED SURGERY,
HE WAS SUCCESSFULLY
TAKEN TO THE RECOVERY
ROOM AND ICU FOR AN
UNKNOWN AMOUNT OF DAYS.
HE SEEMED TO BE DOING
WELL AND PROGRESSING
SUCCESSFULLY OVER THE
NEXT FEW DAYS. HE WAS
DISCHARGED ON THE 25TH OF
JANUARY.

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)	1

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 18:15:13

Generated On: 09 Jun 2021 14:47:56

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) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Name of Medication PROZAC

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Name of Medication DIOVAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 320

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

	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 2000
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22	OCT 2020
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	No <input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication BROKEN RIBS

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	14 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		10 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		10 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Name of Medication ALINIA

Prophylaxis Yes ☐
No ☒

Indication DIARRHEA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Name of Medication DIAVAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 180

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	01 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
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="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Name of Medication BUDESONDIE

Prophylaxis Yes ☐
No ☒

Indication LYMPHOCYTIC COLITIS

Dose per administration 3

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

	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 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

Name of Medication DIORAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 320

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 11:17:53

Generated On: 09 Jun 2021 14:47:56

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

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 24 Feb 2021 00:08:30

Generated On: 09 Jun 2021 14:47:56

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Mar 2021 23:00:00

Generated On: 09 Jun 2021 14:47:56

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
14 JAN 2021	LUNG LOBECTOMY	Adverse Event	
12 NOV 2020	CT OF ABDOMEN	Adverse Event	
11 DEC 2020	COLONOSCOPY	Adverse Event	

US3022186

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 14:47:56

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

US3022186

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 14:47:56

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 ☐

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8
Date of submission (Pre-filled from custom function)	16/OCT/2020 14:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8
Date of submission (Pre-filled from custom function)	05/NOV/2020 11:16
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

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8
Date of submission (Pre-filled from custom function)	10/NOV/2020 14:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8
Date of submission (Pre-filled from custom function)	16/NOV/2020 23:37
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.	True

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8
Date of submission (Pre-filled from custom function)	20/NOV/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

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8
Date of submission (Pre-filled from custom function)	24/NOV/2020 11:03
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

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8
Date of submission (Pre-filled from custom function)	07/APR/2021 13:37
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.	True

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Data signed: (b) (4) 13 Apr 2021 22:18:28

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000009
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)	8
Date of submission (Pre-filled from custom function)	13/APR/2021 16:16
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

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	19/NOV/2020 15:08
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	01/DEC/2020 08:06
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

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	11/DEC/2020 12:04
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Data signed: (b) (4) 25 Mar 2021 23:05:48

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2020-MRNA-1273-P301000012
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	PAUL
Investigator's Last Name	BRADLEY
Site Address: Street	340 EISENHOWER DR.
Site Address: City	SAVANNAH
Site Address: State	GA
Site Address: Postal Code	31406
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	4
Date of submission (Pre-filled from custom function)	22/MAR/2021 13:43
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2021-MRNA-1273-P301000006
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)	5

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2021-MRNA-1273-P301000006
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)	5
Date of submission (Pre-filled from custom function)	22/FEB/2021 13:58
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

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2021-MRNA-1273-P301000006
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)	5
Date of submission (Pre-filled from custom function)	25/FEB/2021 10:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2021-MRNA-1273-P301000006
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)	5
Date of submission (Pre-filled from custom function)	22/MAR/2021 13:44
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2021-MRNA-1273-P301000006
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)	5
Date of submission (Pre-filled from custom function)	13/APR/2021 20:28
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

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 28 Apr 2021 11:17:54

Generated On: 09 Jun 2021 14:47:56

SAEID	USA-US051-2021-MRNA-1273-P301000006
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)	5
Date of submission (Pre-filled from custom function)	21/APR/2021 06:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3022186 (Prod: Meridian Clinical Research-Savannah)

US3022186

Form: Participant Creation

Generated On: 09 Jun 2021 14:47:56

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'US3022186'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 13:44:42

US3022186

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:27:41
	(b) (4)	

US3022186

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '20 AUG 2020'	RWS_ENDPOINT	20 Aug 2020 13:44:43
	ENDPOINT (b) (4)	
	(b) (4)	

US3022186

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Clinic (Clinic)'	Stella Yoon (b) (4)	20 Aug 2020 16:27:41
	(b) (4)	

US3022186

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'SCRN'	(b) (4), (b) (6) System	20 Aug 2020 16:27:41

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered (b) (6) 1954'	RWS_ENDPOINT	20 Aug 2020 13:44:44
	ENDPOINT (b) (4)	
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '66'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'YEARS'	(b) (4), (b) (6) System	20 Aug 2020 16:28:06

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '66'	(b) (4), (b) (6) System	20 Aug 2020 14:41:46

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Male (M)'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 14:47:56

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:06
	(b) (4)	

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '20 Aug 2020'	Shanice Bennett (b) (4)	20 Aug 2020 14:41:46
	(b) (4)	

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Aug 2020'	(b) (4), (b) (6) System	20 Aug 2020 14:41:46

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2020'	(b) (4), (b) (6) System	20 Aug 2020 14:41:46

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Amendment 2 (2)'	Shanice Bennett (b) (4)	20 Aug 2020 14:41:46
	(b) (4)	

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Aug 2020 14:41:46
	(b) (4)	

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 14:41:46
	(b) (4)	

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	20 Aug 2020 14:41:46
	(b) (4)	

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	20 Aug 2020 14:41:46
	(b) (4)	

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	RWS_ENDPOINT	20 Aug 2020 13:44:43
	ENDPOINT (b) (4)	
	(b) (4)	

US3022186

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 14:47:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'I'	(b) (4), (b) (6) System	20 Aug 2020 14:42:24

US3022186

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	20 Aug 2020 14:42:24
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 14:47:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:28:28
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:30:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:30:22
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:29:19
User entered 'hypertension'	Stella Yoon (b) (4)	20 Aug 2020 16:28:53
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un UNK 2000'	Stella Yoon (b) (4)	20 Aug 2020 16:28:53
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:53
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:28:53
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 16:28:53
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:28:53
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Jan 2000'	(b) (4), (b) (6) System	20 Aug 2020 16:28:53

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2000'	(b) (4), (b) (6) System	20 Aug 2020 16:28:53

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 16:28:53

US3022186

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 16:28:53

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:30:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:30:22
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:29:20
User entered 'anxiety'	Stella Yoon (b) (4)	20 Aug 2020 16:29:02
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un UNK 2018'	Stella Yoon (b) (4)	20 Aug 2020 16:29:02
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:29:02
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:29:02
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 16:29:02
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:29:02
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Jan 2018'	(b) (4), (b) (6) System	20 Aug 2020 16:29:02

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2018'	(b) (4), (b) (6) System	20 Aug 2020 16:29:02

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 16:29:02

US3022186

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 16:29:02

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:30:21
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:30:21
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:29:20
User entered 'left knee replacement'	Stella Yoon (b) (4)	20 Aug 2020 16:29:19
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un Nov 2017'	Stella Yoon (b) (4)	20 Aug 2020 16:29:19
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:29:19
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:29:19
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un Nov 2017'	Stella Yoon (b) (4)	20 Aug 2020 16:29:19
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:29:19
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Nov 2017'	(b) (4), (b) (6) System	20 Aug 2020 16:29:19

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2017'	(b) (4), (b) (6) System	20 Aug 2020 16:29:19

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Nov 2017'	(b) (4), (b) (6) System	20 Aug 2020 16:29:19

US3022186

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2017'	(b) (4), (b) (6) System	20 Aug 2020 16:29:19

US3022186

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee arthroplasty, LLT: Knee replacement - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:31:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:31:24
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:30:21
User entered 'right knee replacement'	Stella Yoon (b) (4)	20 Aug 2020 16:29:36
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un Dec 2018'	Stella Yoon (b) (4)	20 Aug 2020 16:29:36
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:29:36
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:29:36
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un Dec 2018'	Stella Yoon (b) (4)	20 Aug 2020 16:29:36
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:29:36
	(b) (4)	

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Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Dec 2018'	(b) (4), (b) (6) System	20 Aug 2020 16:29:36

US3022186

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2018'	(b) (4), (b) (6) System	20 Aug 2020 16:29:36

US3022186

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Dec 2018'	(b) (4), (b) (6) System	20 Aug 2020 16:29:36

US3022186

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2018'	(b) (4), (b) (6) System	20 Aug 2020 16:29:36

US3022186

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to arthropod sting, LLT: Allergic reaction to wasp sting - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:31:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:31:24
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:30:21
User entered 'wasp allergy'	Stella Yoon (b) (4)	20 Aug 2020 16:29:45
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un UNK 2000'	Stella Yoon (b) (4)	20 Aug 2020 16:29:45
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:29:45
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:29:45
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 16:29:45
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:29:45
	(b) (4)	

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Jan 2000'	(b) (4), (b) (6) System	20 Aug 2020 16:29:45

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Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2000'	(b) (4), (b) (6) System	20 Aug 2020 16:29:45

US3022186

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 16:29:45

US3022186

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 16:29:45

US3022186

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:31:24
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:31:24
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:30:23
User entered 'left knee osteoarthritis'	Stella Yoon (b) (4)	20 Aug 2020 16:30:05
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un UNK 2010'	Stella Yoon (b) (4)	20 Aug 2020 16:30:05
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:30:05
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:30:05
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un UNK 2017'	Stella Yoon (b) (4)	20 Aug 2020 16:30:05
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:30:05
	(b) (4)	

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Jan 2010'	(b) (4), (b) (6) System	20 Aug 2020 16:30:05

US3022186

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2010'	(b) (4), (b) (6) System	20 Aug 2020 16:30:05

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Jan 2017'	(b) (4), (b) (6) System	20 Aug 2020 16:30:05

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Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2017'	(b) (4), (b) (6) System	20 Aug 2020 16:30:05

US3022186

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Knee osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:32:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Aug 2020 16:32:22
	(b) (4)	
Data point term sent to Coder	System	20 Aug 2020 16:31:24
User entered 'right knee osteoarthritis'	Stella Yoon (b) (4)	20 Aug 2020 16:30:27
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un UNK 1976'	Stella Yoon (b) (4)	20 Aug 2020 16:30:27
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:30:27
	(b) (4)	

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Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:30:27
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un UNK 2018'	Stella Yoon (b) (4)	20 Aug 2020 16:30:27
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:30:27
	(b) (4)	

US3022186

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Jan 1976'	(b) (4), (b) (6) System	20 Aug 2020 16:30:27

US3022186

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '1976'	(b) (4), (b) (6) System	20 Aug 2020 16:30:27

US3022186

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Jan 2018'	(b) (4), (b) (6) System	20 Aug 2020 16:30:27

US3022186

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2018'	(b) (4), (b) (6) System	20 Aug 2020 16:30:27

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Chronic diarrhea - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 20:13:32
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	26 Oct 2020 20:13:32
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 20:12:47
User entered 'chronic diarrhea'	(b) (4), (b) (6)	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'un UNK 2019'	(b) (4), (b) (6)	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'Jan 2019'	(b) (4), (b) (6) System	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '2019'	(b) (4), (b) (6) System	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered empty.	(b) (4), (b) (6) System	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered empty.	(b) (4), (b) (6) System	26 Oct 2020 20:12:42

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '09:47'	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered '20 Aug 2020 09:47'	(b) (4), (b) (6) System	20 Aug 2020 16:31:49

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '170.1' cm	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 14:42:24

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '70.2' kg	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	
DataPoint set to visible.	System	20 Aug 2020 14:42:24

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
Amendment Manager: User entered '24.26211'	(b) (4), (b) (6)	
User entered '24.3'	System	17 Sep 2020 00:15:40
DataPoint set to visible.	System	20 Aug 2020 16:31:49
	System	20 Aug 2020 14:42:24

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User entered 'kg/m2'	System	20 Aug 2020 16:31:49
DataPoint set to visible.	System	20 Aug 2020 14:42:24

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
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)	13 Nov 2020 05:24:42
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)	12 Nov 2020 14:21:23
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:21:12
User opened query 'Per CDM: Per CCGs V2.0 pages 16-17, if Screening and Visit 1 Day 1 are on the same day, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP on this page (ND for "Not done" and not left empty). Please note that when ND is recorded the units should not remain. Please review and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 10:22:45
User entered '36.9' C	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:31:49

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:21:12
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:21:12
	(b) (4)	
User entered '87'	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'bpm'	(b) (4), (b) (6) System	20 Aug 2020 16:31:49

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:21:12
	(b) (4)	
User entered '15'	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Aug 2020 16:31:49

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:21:12
	(b) (4)	
User entered '144'	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 16:31:49

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:21:12
	(b) (4)	
User entered '90'	Stella Yoon (b) (4)	20 Aug 2020 16:31:49
	(b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 16:31:49

US3022186

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:31:12

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	26 Apr 2021 13:31:12

US3022186

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:31:56
	(b) (4)	

US3022186

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 16:31:56
	(b) (4)	

US3022186

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

US3022186

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

US3022186

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

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Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'painting contractor'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'I'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 14:47:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 13:31:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'ongoing person to person transmission'	Stella Yoon (b) (4)	20 Aug 2020 16:32:42
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:33:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 16:33:23
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Clinic (Clinic)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:33:23

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'VISIT1'	(b) (4), (b) (6) System	20 Aug 2020 16:33:23

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 14:15:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:48:46
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:48:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 14:15:24
User entered '187100' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4) (b) (4)	20 Aug 2020 14:15:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '>=65 years (3)'	RWS_ENDPOINT	20 Aug 2020 14:15:24
	ENDPOINT (b) (4)	
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:33:41

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:33:41

US3022186

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:33:41
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:33:41
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 16:33:41
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 14:47:56

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User closed query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Nov 2020 11:23:31
Query 'Per CDM: This field requires yes or no. Please complete. ' answered with 'UPDATED' (Site from DM).	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 18:34:07
User entered 'No (N)'	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 18:34:02
User opened query 'Per CDM: This field requires yes or no. Please complete. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 16:53:43
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:36:41
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:41:49

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
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)	13 Nov 2020 06:34:26
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)	12 Nov 2020 14:15:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:15:48
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:15:36
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:08:11
User entered '170.1' cm	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:15:48
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:15:36
	(b) (4)	
User entered '70.2' kg	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
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)	13 Nov 2020 06:34:26
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)	12 Nov 2020 14:15:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:15:48
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:15:36
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:08:11
User entered '170.1' cm	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

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[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:15:48
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:15:36
	(b) (4)	
User entered '70.2' kg	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User accepted default value 'Pre-Dose (PREDOSE)'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '20 Aug 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '09:47'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '20 Aug 2020 09:47'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '36.9' C	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '87'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'bpm'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '15'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '144'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '90'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
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)	13 Nov 2020 06:34:26
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)	12 Nov 2020 14:15:57
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:15:48
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4) (b) (4)	12 Nov 2020 14:15:36
User opened query 'Per CDM Please note as the Screening and Visit 1 is done on the same day, Height and weight to be recorded in screening and updated to "NOT Done " in Visit 1. Kindly remove the units as well .Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 10:08:11
User entered '170.1' cm	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered missing code ND - Not Done; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:15:48
	(b) (4)	
User entered empty; reason for change Per Query Resolution	Morgan Deal (b) (4)	12 Nov 2020 14:15:36
	(b) (4)	
User entered '70.2' kg	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '20 Aug 2020'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:17:02
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:43
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)	20 Aug 2020 16:36:31
User opened 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).	System	20 Aug 2020 16:36:13
User entered '10:58'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '20 Aug 2020 10:58'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '36.8' C	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Oral (Oral)'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '81'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'bpm'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '15'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'breaths/min'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '121'	Stella Yoon (b) (4)	20 Aug 2020 16:36:13
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '86'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 16:36:13

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'mmHg'	(b) (4), (b) (6) System	20 Aug 2020 16:36:13

US3022186

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 16:36:39
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 16:36:39
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 14:43:10

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Aug 2020 14:43:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered empty.	(b) (4) Shanice Bennett (b) (4)	20 Aug 2020 14:43:10
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '20 Aug 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	20 Aug 2020 14:43:10

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '10:26'	Shanice Bennett (b) (4)	20 Aug 2020 14:43:10
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '20 Aug 2020 10:26'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) Shanice Bennett (b) (4)	20 Aug 2020 14:43:10

US3022186

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'ONCE'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 17:01:49
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 17:01:49
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '09:58'	Stella Yoon (b) (4)	20 Aug 2020 17:01:49
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '20 Aug 2020 09:58'	(b) (4), (b) (6) System	20 Aug 2020 17:01:49

US3022186

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:47:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '20 Aug 2020'	Stella Yoon (b) (4)	20 Aug 2020 17:01:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:01:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:01:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '10:09'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:01:59

US3022186

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '20 Aug 2020 10:09'	(b) (4), (b) (6) System	20 Aug 2020 17:01:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:01:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:01:59

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 17:01:59
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered empty.	(b) (4), (b) (6) System	20 Aug 2020 17:01:59

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Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 17:02:03
	(b) (4)	

US3022186

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	20 Aug 2020 17:02:03

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:00:47', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a5c65b7d-df59-4f9d-affe-b0a48e67b6ac' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 15:01:28
	System	20 Aug 2020 15:01:28

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:00:58', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a5c65b7d-df59-4f9d-affe-b0a48e67b6ac' User entered '98.4'	(b) (4), (b) (6) System	20 Aug 2020 15:01:28
	System	20 Aug 2020 15:01:28

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:01:04', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a5c65b7d-df59-4f9d-affe-b0a48e67b6ac'	(b) (4), (b) (6)	
	System	20 Aug 2020 15:01:28
User entered 'No (N)'	System	20 Aug 2020 15:01:28

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:01:22', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a5c65b7d-df59-4f9d-affe-b0a48e67b6ac'	(b) (4), (b) (6) System	20 Aug 2020 15:01:28
User entered '20 Aug 2020 11:01'	System	20 Aug 2020 15:01:28

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 10:46'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 13:16'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:56:30', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '5e3c666c-588c-47d2-ab40-ce8bd15166f0' User entered 'Yes (Y)'	(b) (4), (b) (6) System	20 Aug 2020 23:57:07
	System	20 Aug 2020 23:57:07

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:56:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '5e3c666c-588c-47d2-ab40-ce8bd15166f0' User entered '97.2'	(b) (4), (b) (6) System	20 Aug 2020 23:57:07
	System	20 Aug 2020 23:57:07

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:56:43', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '5e3c666c-588c-47d2-ab40-ce8bd15166f0' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 23:57:07
	System	20 Aug 2020 23:57:07

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:57:05', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '5e3c666c-588c-47d2-ab40-ce8bd15166f0' User entered '20 Aug 2020 19:57'	(b) (4), (b) (6) System	20 Aug 2020 23:57:07
	System	20 Aug 2020 23:57:07

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 14:11'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 2'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:00:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '650f3c9b-a655-44e4-9025-40598f78c0c8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 00:01:09
	System	22 Aug 2020 00:01:09

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:00:46', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '650f3c9b-a655-44e4-9025-40598f78c0c8' User entered '97.6'	(b) (4), (b) (6) System	22 Aug 2020 00:01:09
	System	22 Aug 2020 00:01:09

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:00:53', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '650f3c9b-a655-44e4-9025-40598f78c0c8' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 00:01:09
	System	22 Aug 2020 00:01:09

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:01:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '650f3c9b-a655-44e4-9025-40598f78c0c8' User entered '21 Aug 2020 20:01'	(b) (4), (b) (6) System	22 Aug 2020 00:01:09
	System	22 Aug 2020 00:01:09

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 3'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:46:21', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6f7b269d-255c-4019-b003-52d215224f09' User entered 'Yes (Y)'	(b) (4), (b) (6) System	22 Aug 2020 23:46:53
	System	22 Aug 2020 23:46:53

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:46:29', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6f7b269d-255c-4019-b003-52d215224f09' User entered '97.3'	(b) (4), (b) (6) System	22 Aug 2020 23:46:53
	System	22 Aug 2020 23:46:53

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:46:36', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6f7b269d-255c-4019-b003-52d215224f09' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:46:53
	System	22 Aug 2020 23:46:53

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:46:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6f7b269d-255c-4019-b003-52d215224f09' User entered '22 Aug 2020 19:46'	(b) (4), (b) (6) System	22 Aug 2020 23:46:53
	System	22 Aug 2020 23:46:53

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 4'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:21:57', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '13d520be-35f1-4e77-aa23-89eef54f323e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	23 Aug 2020 23:23:27
	System	23 Aug 2020 23:23:27

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:23:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '13d520be-35f1-4e77-aa23-89eef54f323e' User entered '96.9'	(b) (4), (b) (6) System	23 Aug 2020 23:23:27
	System	23 Aug 2020 23:23:27

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:23:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '13d520be-35f1-4e77-aa23-89eef54f323e' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:23:27
	System	23 Aug 2020 23:23:27

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:23:25', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '13d520be-35f1-4e77-aa23-89eef54f323e' User entered '23 Aug 2020 19:23'	(b) (4), (b) (6) System	23 Aug 2020 23:23:27
	System	23 Aug 2020 23:23:27

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 5'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T18:58:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7890d18c-99cf-44a1-b504-a1f70fa9f8d8'	(b) (4), (b) (6)	
	System	24 Aug 2020 23:00:23
User entered 'Yes (Y)'	System	24 Aug 2020 23:00:23

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T18:59:53', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7890d18c-99cf-44a1-b504-a1f70fa9f8d8' User entered '99.2'	(b) (4), (b) (6) System	24 Aug 2020 23:00:23
	System	24 Aug 2020 23:00:23

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:00:02', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7890d18c-99cf-44a1-b504-a1f70fa9f8d8'	(b) (4), (b) (6)	24 Aug 2020 23:00:23
User entered 'No (N)'	System	24 Aug 2020 23:00:23

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:00:20', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7890d18c-99cf-44a1-b504-a1f70fa9f8d8' User entered '24 Aug 2020 19:00'	(b) (4), (b) (6) System	24 Aug 2020 23:00:23
	System	24 Aug 2020 23:00:23

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 6'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:08:33', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7d5761e1-d305-48be-8c52-201eaa31a68e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Aug 2020 00:11:34
	System	26 Aug 2020 00:11:34

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:11:09', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7d5761e1-d305-48be-8c52-201eaa31a68e' User entered '97.2'	(b) (4), (b) (6) System	26 Aug 2020 00:11:34
	System	26 Aug 2020 00:11:34

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:11:20', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7d5761e1-d305-48be-8c52-201eaa31a68e' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 00:11:34
	System	26 Aug 2020 00:11:34

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:11:30', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7d5761e1-d305-48be-8c52-201eaa31a68e' User entered '25 Aug 2020 20:11'	(b) (4), (b) (6) System	26 Aug 2020 00:11:34
	System	26 Aug 2020 00:11:34

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 7'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:43:43', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'd979e52e-9e69-438a-8235-201a2161e109'	(b) (4), (b) (6)	26 Aug 2020 21:49:10
User entered 'Yes (Y)'	System	26 Aug 2020 21:49:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:48:48', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'd979e52e-9e69-438a-8235-201a2161e109' User entered '97.3'	(b) (4), (b) (6) System	26 Aug 2020 21:49:10
	System	26 Aug 2020 21:49:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:48:55', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'd979e52e-9e69-438a-8235-201a2161e109'	(b) (4), (b) (6)	26 Aug 2020 21:49:10
User entered 'No (N)'	System	26 Aug 2020 21:49:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'd979e52e-9e69-438a-8235-201a2161e109' User entered '26 Aug 2020 17:49'	(b) (4), (b) (6) System	26 Aug 2020 21:49:10
	System	26 Aug 2020 21:49:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:01:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1ccd87f0-5772-412b-83a8-1b3d0dcf839c'	(b) (4), (b) (6) System	20 Aug 2020 15:02:31
User entered 'None (1)'	System	20 Aug 2020 15:02:31

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:02:01', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1ccd87f0-5772-412b-83a8-1b3d0dcf839c'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 15:02:31

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:02:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1ccd87f0-5772-412b-83a8-1b3d0dcf839c' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 15:02:31
	System	20 Aug 2020 15:02:31

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:02:18', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1ccd87f0-5772-412b-83a8-1b3d0dcf839c' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 15:02:31
	System	20 Aug 2020 15:02:31

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:02:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1ccd87f0-5772-412b-83a8-1b3d0dcf839c' User entered '20 Aug 2020 11:02'	(b) (4), (b) (6) System	20 Aug 2020 15:02:31
	System	20 Aug 2020 15:02:31

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 10:46'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 13:16'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:57:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '07334550-b533-4434-8be4-64e52ebeca50'	(b) (4), (b) (6)	20 Aug 2020 23:57:57
User entered 'None (1)'	System	20 Aug 2020 23:57:57

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:57:24', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '07334550-b533-4434-8be4-64e52ebeca50'	(b) (4), (b) (6)	20 Aug 2020 23:57:57
User entered 'No (N)'	System	20 Aug 2020 23:57:57

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:57:30', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '07334550-b533-4434-8be4-64e52ebeca50'	(b) (4), (b) (6)	
User entered 'No (N)'	System	20 Aug 2020 23:57:57

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:57:40', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '07334550-b533-4434-8be4-64e52ebeca50' User entered 'None (1)'	(b) (4), (b) (6) System	20 Aug 2020 23:57:57
	System	20 Aug 2020 23:57:57

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:57:53', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '07334550-b533-4434-8be4-64e52ebeca50' User entered '20 Aug 2020 19:57'	(b) (4), (b) (6) System	20 Aug 2020 23:57:57
	System	20 Aug 2020 23:57:57

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 14:11'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 2'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:01:17', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'be05ff97-b2d4-46bc-9e3f-a706421546cb'	(b) (4), (b) (6) System	22 Aug 2020 00:01:58
User entered 'None (1)'	System	22 Aug 2020 00:01:58

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:01:23', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'be05ff97-b2d4-46bc-9e3f-a706421546cb' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 00:01:58
	System	22 Aug 2020 00:01:58

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:01:34', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'be05ff97-b2d4-46bc-9e3f-a706421546cb' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 00:01:58
	System	22 Aug 2020 00:01:58

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:01:43', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'be05ff97-b2d4-46bc-9e3f-a706421546cb' User entered 'None (1)'	(b) (4), (b) (6) System	22 Aug 2020 00:01:58
	System	22 Aug 2020 00:01:58

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:01:56', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'be05ff97-b2d4-46bc-9e3f-a706421546cb' User entered '21 Aug 2020 20:01'	(b) (4), (b) (6) System	22 Aug 2020 00:01:58
	System	22 Aug 2020 00:01:58

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 3'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:46:57', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '39fe6351-06b7-4aff-aae8-51c3da6b4f5f'	(b) (4), (b) (6) System	22 Aug 2020 23:47:27
User entered 'None (1)'	System	22 Aug 2020 23:47:27

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:01', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '39fe6351-06b7-4aff-aae8-51c3da6b4f5f'	(b) (4), (b) (6)	22 Aug 2020 23:47:27
User entered 'No (N)'	System	22 Aug 2020 23:47:27

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '39fe6351-06b7-4aff-aae8-51c3da6b4f5f' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:47:27
	System	22 Aug 2020 23:47:27

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:15', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '39fe6351-06b7-4aff-aae8-51c3da6b4f5f'	(b) (4), (b) (6) System	22 Aug 2020 23:47:27
User entered 'None (1)'	System	22 Aug 2020 23:47:27

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:24', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '39fe6351-06b7-4aff-aae8-51c3da6b4f5f' User entered '22 Aug 2020 19:47'	(b) (4), (b) (6) System	22 Aug 2020 23:47:27
	System	22 Aug 2020 23:47:27

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 4'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:23:33', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d6ea1c8-1807-425a-8df7-18696fb52012'	(b) (4), (b) (6) System	23 Aug 2020 23:23:55
User entered 'None (1)'	System	23 Aug 2020 23:23:55

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:23:38', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d6ea1c8-1807-425a-8df7-18696fb52012' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:23:55
	System	23 Aug 2020 23:23:55

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:23:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d6ea1c8-1807-425a-8df7-18696fb52012' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:23:55
	System	23 Aug 2020 23:23:55

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:23:48', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d6ea1c8-1807-425a-8df7-18696fb52012' User entered 'None (1)'	(b) (4), (b) (6) System	23 Aug 2020 23:23:55
	System	23 Aug 2020 23:23:55

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:23:53', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d6ea1c8-1807-425a-8df7-18696fb52012'	(b) (4), (b) (6) System	23 Aug 2020 23:23:55
User entered '23 Aug 2020 19:23'	System	23 Aug 2020 23:23:55

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 5'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:00:33', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e28edba3-d058-4a3f-b183-928653e787f0' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 23:01:17
	System	24 Aug 2020 23:01:17

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:00:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e28edba3-d058-4a3f-b183-928653e787f0' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:01:17
	System	24 Aug 2020 23:01:17

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:00:51', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e28edba3-d058-4a3f-b183-928653e787f0' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:01:17
	System	24 Aug 2020 23:01:17

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:04', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e28edba3-d058-4a3f-b183-928653e787f0' User entered 'None (1)'	(b) (4), (b) (6) System	24 Aug 2020 23:01:17
	System	24 Aug 2020 23:01:17

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e28edba3-d058-4a3f-b183-928653e787f0' User entered '24 Aug 2020 19:01'	(b) (4), (b) (6) System	24 Aug 2020 23:01:17
	System	24 Aug 2020 23:01:17

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 6'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:11:44', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f51337fb-7842-48e5-9573-b03db4a11ef4'	(b) (4), (b) (6) System	26 Aug 2020 00:12:20
User entered 'None (1)'	System	26 Aug 2020 00:12:20

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:11:52', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f51337fb-7842-48e5-9573-b03db4a11ef4'	(b) (4), (b) (6) System	26 Aug 2020 00:12:20
User entered 'No (N)'	System	26 Aug 2020 00:12:20

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:11:59', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f51337fb-7842-48e5-9573-b03db4a11ef4'	(b) (4), (b) (6)	
	System	26 Aug 2020 00:12:20
User entered 'No (N)'	System	26 Aug 2020 00:12:20

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:12:09', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f51337fb-7842-48e5-9573-b03db4a11ef4' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 00:12:20
	System	26 Aug 2020 00:12:20

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:12:17', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f51337fb-7842-48e5-9573-b03db4a11ef4'	(b) (4), (b) (6) System	26 Aug 2020 00:12:20
User entered '25 Aug 2020 20:12'	System	26 Aug 2020 00:12:20

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 7'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:15', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c8b4ea4b-3553-4934-80b2-32d8248e82b4' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 21:49:41
	System	26 Aug 2020 21:49:41

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c8b4ea4b-3553-4934-80b2-32d8248e82b4' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 21:49:41
	System	26 Aug 2020 21:49:41

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:24', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c8b4ea4b-3553-4934-80b2-32d8248e82b4' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 21:49:41
	System	26 Aug 2020 21:49:41

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:29', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c8b4ea4b-3553-4934-80b2-32d8248e82b4' User entered 'None (1)'	(b) (4), (b) (6) System	26 Aug 2020 21:49:41
	System	26 Aug 2020 21:49:41

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c8b4ea4b-3553-4934-80b2-32d8248e82b4' User entered '26 Aug 2020 17:49'	(b) (4), (b) (6) System	26 Aug 2020 21:49:41
	System	26 Aug 2020 21:49:41

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:02:40', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f88ea9de-2e6e-4398-91c2-986855bd20fe' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 15:03:34
	System	20 Aug 2020 15:03:34

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:02:51', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f88ea9de-2e6e-4398-91c2-986855bd20fe' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 15:03:34
	System	20 Aug 2020 15:03:34

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:02:57', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f88ea9de-2e6e-4398-91c2-986855bd20fe' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 15:03:34
	System	20 Aug 2020 15:03:34

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:03:03', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f88ea9de-2e6e-4398-91c2-986855bd20fe' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 15:03:34
	System	20 Aug 2020 15:03:34

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:03:07', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f88ea9de-2e6e-4398-91c2-986855bd20fe' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 15:03:34
	System	20 Aug 2020 15:03:34

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:03:10', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f88ea9de-2e6e-4398-91c2-986855bd20fe' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 15:03:34
	System	20 Aug 2020 15:03:34

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:03:21', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f88ea9de-2e6e-4398-91c2-986855bd20fe' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 15:03:34
	System	20 Aug 2020 15:03:34

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T11:03:31', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f88ea9de-2e6e-4398-91c2-986855bd20fe' User entered '20 Aug 2020 11:03'	(b) (4), (b) (6) System	20 Aug 2020 15:03:34
	System	20 Aug 2020 15:03:34

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 10:46'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 13:16'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:58:04', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e13388a9-6da5-4d74-bef8-8a5dbb176000' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:59:02
	System	20 Aug 2020 23:59:02

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:58:12', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e13388a9-6da5-4d74-bef8-8a5dbb176000' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:59:02
	System	20 Aug 2020 23:59:02

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:58:18', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e13388a9-6da5-4d74-bef8-8a5dbb176000' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:59:02
	System	20 Aug 2020 23:59:02

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:58:24', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e13388a9-6da5-4d74-bef8-8a5dbb176000' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:59:02
	System	20 Aug 2020 23:59:02

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:58:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e13388a9-6da5-4d74-bef8-8a5dbb176000' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:59:02
	System	20 Aug 2020 23:59:02

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:58:31', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e13388a9-6da5-4d74-bef8-8a5dbb176000' User entered 'None (0)'	(b) (4), (b) (6) System	20 Aug 2020 23:59:02
	System	20 Aug 2020 23:59:02

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:58:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e13388a9-6da5-4d74-bef8-8a5dbb176000' User entered 'No (N)'	(b) (4), (b) (6) System	20 Aug 2020 23:59:02
	System	20 Aug 2020 23:59:02

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-20T19:58:58', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e13388a9-6da5-4d74-bef8-8a5dbb176000' User entered '20 Aug 2020 19:58'	(b) (4), (b) (6) System	20 Aug 2020 23:59:02
	System	20 Aug 2020 23:59:02

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '20 Aug 2020 14:11'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '21 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 2'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:02:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '99aa13dd-1190-4381-885e-9ea4110b9c63' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:03:11
	System	22 Aug 2020 00:03:11

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:02:17', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '99aa13dd-1190-4381-885e-9ea4110b9c63' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:03:11
	System	22 Aug 2020 00:03:11

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:02:23', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '99aa13dd-1190-4381-885e-9ea4110b9c63' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:03:11
	System	22 Aug 2020 00:03:11

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:02:29', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '99aa13dd-1190-4381-885e-9ea4110b9c63' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:03:11
	System	22 Aug 2020 00:03:11

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:02:33', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '99aa13dd-1190-4381-885e-9ea4110b9c63' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:03:11
	System	22 Aug 2020 00:03:11

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:02:38', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '99aa13dd-1190-4381-885e-9ea4110b9c63' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 00:03:11
	System	22 Aug 2020 00:03:11

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:02:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '99aa13dd-1190-4381-885e-9ea4110b9c63'	(b) (4), (b) (6)	
	System	22 Aug 2020 00:03:11
User entered 'No (N)'	System	22 Aug 2020 00:03:11

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-21T20:03:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '99aa13dd-1190-4381-885e-9ea4110b9c63' User entered '21 Aug 2020 20:03'	(b) (4), (b) (6) System	22 Aug 2020 00:03:11
	System	22 Aug 2020 00:03:11

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '21 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '22 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 3'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:32', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f27c29e4-b464-4ae4-9810-c188a6004afe' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:48:16
	System	22 Aug 2020 23:48:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f27c29e4-b464-4ae4-9810-c188a6004afe' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:48:16
	System	22 Aug 2020 23:48:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f27c29e4-b464-4ae4-9810-c188a6004afe' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:48:16
	System	22 Aug 2020 23:48:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:47', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f27c29e4-b464-4ae4-9810-c188a6004afe' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:48:16
	System	22 Aug 2020 23:48:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:51', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f27c29e4-b464-4ae4-9810-c188a6004afe' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:48:16
	System	22 Aug 2020 23:48:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:47:54', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f27c29e4-b464-4ae4-9810-c188a6004afe' User entered 'None (0)'	(b) (4), (b) (6) System	22 Aug 2020 23:48:16
	System	22 Aug 2020 23:48:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:48:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f27c29e4-b464-4ae4-9810-c188a6004afe' User entered 'No (N)'	(b) (4), (b) (6) System	22 Aug 2020 23:48:16
	System	22 Aug 2020 23:48:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-22T19:48:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'f27c29e4-b464-4ae4-9810-c188a6004afe' User entered '22 Aug 2020 19:48'	(b) (4), (b) (6) System	22 Aug 2020 23:48:16
	System	22 Aug 2020 23:48:16

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '22 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '23 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 4'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:24:01', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '41e8b927-71c1-46e1-89db-04363fc4bbb5' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:24:51
	System	23 Aug 2020 23:24:51

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:24:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '41e8b927-71c1-46e1-89db-04363fc4bbb5' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:24:51
	System	23 Aug 2020 23:24:51

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:24:11', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '41e8b927-71c1-46e1-89db-04363fc4bbb5' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:24:51
	System	23 Aug 2020 23:24:51

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:24:16', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '41e8b927-71c1-46e1-89db-04363fc4bbb5' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:24:51
	System	23 Aug 2020 23:24:51

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:24:20', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '41e8b927-71c1-46e1-89db-04363fc4bbb5' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:24:51
	System	23 Aug 2020 23:24:51

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:24:25', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '41e8b927-71c1-46e1-89db-04363fc4bbb5' User entered 'None (0)'	(b) (4), (b) (6) System	23 Aug 2020 23:24:51
	System	23 Aug 2020 23:24:51

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:24:36', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '41e8b927-71c1-46e1-89db-04363fc4bbb5' User entered 'No (N)'	(b) (4), (b) (6) System	23 Aug 2020 23:24:51
	System	23 Aug 2020 23:24:51

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-23T19:24:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '41e8b927-71c1-46e1-89db-04363fc4bbb5' User entered '23 Aug 2020 19:24'	(b) (4), (b) (6) System	23 Aug 2020 23:24:51
	System	23 Aug 2020 23:24:51

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '23 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 5'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'fad4cb9f-4abb-4689-94d4-6dee63ec7fa9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:02:13
	System	24 Aug 2020 23:02:13

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:33', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'fad4cb9f-4abb-4689-94d4-6dee63ec7fa9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:02:13
	System	24 Aug 2020 23:02:13

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'fad4cb9f-4abb-4689-94d4-6dee63ec7fa9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:02:13
	System	24 Aug 2020 23:02:13

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:41', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'fad4cb9f-4abb-4689-94d4-6dee63ec7fa9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:02:13
	System	24 Aug 2020 23:02:13

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:44', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'fad4cb9f-4abb-4689-94d4-6dee63ec7fa9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:02:13
	System	24 Aug 2020 23:02:13

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:47', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'fad4cb9f-4abb-4689-94d4-6dee63ec7fa9' User entered 'None (0)'	(b) (4), (b) (6) System	24 Aug 2020 23:02:13
	System	24 Aug 2020 23:02:13

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:01:53', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'fad4cb9f-4abb-4689-94d4-6dee63ec7fa9' User entered 'No (N)'	(b) (4), (b) (6) System	24 Aug 2020 23:02:13
	System	24 Aug 2020 23:02:13

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-24T19:02:07', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'fad4cb9f-4abb-4689-94d4-6dee63ec7fa9'	(b) (4), (b) (6) System	24 Aug 2020 23:02:13
User entered '24 Aug 2020 19:02'	System	24 Aug 2020 23:02:13

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 6'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:12:29', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6c4bd614-0fcf-4bf0-98a0-feda4eae1724' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 00:13:27
	System	26 Aug 2020 00:13:27

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:12:36', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6c4bd614-0fcf-4bf0-98a0-feda4cae1724' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 00:13:27
	System	26 Aug 2020 00:13:27

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:12:41', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6c4bd614-0fcf-4bf0-98a0-feda4eae1724' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 00:13:27
	System	26 Aug 2020 00:13:27

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:12:47', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6c4bd614-0fcf-4bf0-98a0-feda4eae1724' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 00:13:27
	System	26 Aug 2020 00:13:27

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:12:51', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6c4bd614-0fcf-4bf0-98a0-feda4eae1724' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 00:13:27
	System	26 Aug 2020 00:13:27

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:12:55', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6c4bd614-0fcf-4bf0-98a0-feda4eae1724' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 00:13:27
	System	26 Aug 2020 00:13:27

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:13:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6c4bd614-0fcf-4bf0-98a0-feda4eae1724' User entered 'No (N)'	(b) (4), (b) (6) System	26 Aug 2020 00:13:27
	System	26 Aug 2020 00:13:27

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-25T20:13:26', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6c4bd614-0fcf-4bf0-98a0-feda4eae1724' User entered '25 Aug 2020 20:13'	(b) (4), (b) (6) System	26 Aug 2020 00:13:27
	System	26 Aug 2020 00:13:27

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 7'	System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:46', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '69b75d9a-5ae4-400d-807f-ad896cee49' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 21:50:22
	System	26 Aug 2020 21:50:22

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:50', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '69b75d9a-5ae4-400d-807f-ad896cee49' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 21:50:22
	System	26 Aug 2020 21:50:22

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:49:55', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '69b75d9a-5ae4-400d-807f-ad896cee49' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 21:50:22
	System	26 Aug 2020 21:50:22

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:50:01', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '69b75d9a-5ae4-400d-807f-ad896cee49'	(b) (4), (b) (6)	26 Aug 2020 21:50:22
User entered 'None (0)'	System	26 Aug 2020 21:50:22

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:50:05', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '69b75d9a-5ae4-400d-807f-ad896cee49' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 21:50:22
	System	26 Aug 2020 21:50:22

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:50:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '69b75d9a-5ae4-400d-807f-ad896cee49' User entered 'None (0)'	(b) (4), (b) (6) System	26 Aug 2020 21:50:22
	System	26 Aug 2020 21:50:22

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:50:16', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '69b75d9a-5ae4-400d-807f-ad896cee49'	(b) (4), (b) (6)	26 Aug 2020 21:50:22
User entered 'No (N)'	System	26 Aug 2020 21:50:22

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-08-26T17:50:20', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '69b75d9a-5ae4-400d-807f-ad896cee49'	(b) (4), (b) (6) System	26 Aug 2020 21:50:22
User entered '26 Aug 2020 17:50'	System	26 Aug 2020 21:50:22

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Aug 2020 12:00'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Aug 2020 11:59'	(b) (4), (b) (6) System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:45:30

US3022186

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '27 Aug 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:45:30

US3022186

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:45:30

US3022186

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:45:30

US3022186

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Sep 2020 13:45:37

US3022186

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	22 Sep 2020 13:45:37

US3022186

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:46:40

US3022186

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:46:40

US3022186

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:46:40

US3022186

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:46:40

US3022186

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:46:45

US3022186

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	22 Sep 2020 13:46:45

US3022186

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:47:47

US3022186

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:47:47

US3022186

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:47:47

US3022186

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	22 Sep 2020 13:47:47

US3022186

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Sep 2020 13:47:52

US3022186

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	22 Sep 2020 13:47:52

US3022186

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:24

US3022186

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 19:01:24

US3022186

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Sep 2020 19:01:24

US3022186

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'VISIT2'	(b) (4), (b) (6) System	24 Sep 2020 19:01:24

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User closed query 'Per CDM: As per CCG: data is required, please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	18 Dec 2020 13:03:22
Query 'Per CDM: As per CCG: data is required, please review and update accordingly. ' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 14:08:19
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	17 Dec 2020 14:08:10
User opened query 'Per CDM: As per CCG: data is required, please review and update accordingly. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 04:30:25

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '11:28'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '24 Sep 2020 11:28'	(b) (4), (b) (6) System	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '36.9' C	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:17:02
User closed query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Dec 2020 14:08:38
Query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Dec 2020 14:08:38
User entered '71' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 14:08:38
User opened query 'Pulse reported is out of range < 45 or > 130 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Dec 2020 14:08:10
User entered '16'	(b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'bpm'	(b) (4), (b) (6) System	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:17:02
User closed query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Dec 2020 14:08:38
Query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered by data change (Site from System).	System	17 Dec 2020 14:08:38
User entered '16' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 14:08:38
User opened query 'Respiratory rate reported is out of range < 8 or > 32 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Dec 2020 14:08:10
User entered '71'	(b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '138'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'mmHg'	(b) (4), (b) (6) System	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '86'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'mmHg'	(b) (4), (b) (6) System	17 Dec 2020 14:08:10

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Date of assessment \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '12:32'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '24 Sep 2020 12:32'	(b) (4), (b) (6) System	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '59'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'bpm'	(b) (4), (b) (6) System	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '14'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'breaths/min'	(b) (4), (b) (6) System	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '126'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'mmHg'	(b) (4), (b) (6) System	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '78'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'mmHg'	(b) (4), (b) (6) System	17 Dec 2020 14:09:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:01:39

US3022186

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '24 Sep 2020'	(b) (4), (b) (6)	24 Sep 2020 19:01:39

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 16:17:41

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	24 Sep 2020 16:17:41
	(b) (4)	

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered empty.	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 16:17:41
	(b) (4)	

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'MRNA-1273 OR PLACEBO'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '24 Sep 2020'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 16:17:41

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '12:01'	Chevon Roberts (b) (4)	24 Sep 2020 16:17:41
	(b) (4)	

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '24 Sep 2020 12:01'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Left Arm (LEFT ARM)'	(b) (4) Chevon Roberts (b) (4)	24 Sep 2020 16:17:41

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'ONCE'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'INTRAMUSCULAR'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:02:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:02:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '11:38'	(b) (4), (b) (6)	24 Sep 2020 19:02:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '24 Sep 2020 11:38'	(b) (4), (b) (6) System	24 Sep 2020 19:02:14

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 14:47:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '24 Sep 2020'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '11:41'	(b) (4), (b) (6)	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered '24 Sep 2020 11:41'	(b) (4), (b) (6) System	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered empty.	(b) (4), (b) (6) System	24 Sep 2020 19:02:29

US3022186

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Sep 2020 19:02:37

US3022186

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	24 Sep 2020 19:02:37

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:33:27', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dfb9bdf0-998c-4bf7-bbcd-aacea54656a4' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 16:34:03
	System	24 Sep 2020 16:34:03

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:33:36', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dfb9bdf0-998c-4bf7-bbcd-aacea54656a4' User entered '98.1'	(b) (4), (b) (6) System	24 Sep 2020 16:34:03
	System	24 Sep 2020 16:34:03

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:33:45', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dfb9bdf0-998c-4bf7-bbcd-aacea54656a4'	(b) (4), (b) (6)	24 Sep 2020 16:34:03
User entered 'No (N)'	System	24 Sep 2020 16:34:03

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:33:57', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dfb9bdf0-998c-4bf7-bbcd-aacea54656a4' User entered '24 Sep 2020 12:33'	(b) (4), (b) (6) System	24 Sep 2020 16:34:03
	System	24 Sep 2020 16:34:03

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 12:21'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 14:51'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:16:30', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2ed7f11b-c6ce-410d-b521-2c3f3e675638' User entered 'Yes (Y)'	(b) (4), (b) (6) System	24 Sep 2020 22:17:54
	System	24 Sep 2020 22:17:54

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:17:36', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2ed7f11b-c6ce-410d-b521-2c3f3e675638' User entered '98.4'	(b) (4), (b) (6) System	24 Sep 2020 22:17:54
	System	24 Sep 2020 22:17:54

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:17:41', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2ed7f11b-c6ce-410d-b521-2c3f3e675638' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 22:17:54
	System	24 Sep 2020 22:17:54

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:17:51', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2ed7f11b-c6ce-410d-b521-2c3f3e675638' User entered '24 Sep 2020 18:17'	(b) (4), (b) (6) System	24 Sep 2020 22:17:54
	System	24 Sep 2020 22:17:54

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 15:46'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 2'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:07:09', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1da6f317-9475-439b-a451-536a94e66f1e' User entered 'Yes (Y)'	(b) (4), (b) (6) System	25 Sep 2020 22:08:32
	System	25 Sep 2020 22:08:32

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:08:03', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1da6f317-9475-439b-a451-536a94e66f1e' User entered '97.9'	(b) (4), (b) (6) System	25 Sep 2020 22:08:32
	System	25 Sep 2020 22:08:32

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:08:10', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1da6f317-9475-439b-a451-536a94e66f1e' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 22:08:32
	System	25 Sep 2020 22:08:32

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:08:27', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1da6f317-9475-439b-a451-536a94e66f1e' User entered '25 Sep 2020 18:08'	(b) (4), (b) (6) System	25 Sep 2020 22:08:32
	System	25 Sep 2020 22:08:32

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 3'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:21:01', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c43d78ee-7693-466b-9f68-9145445131b8' User entered 'Yes (Y)'	(b) (4), (b) (6) System	26 Sep 2020 19:21:42
	System	26 Sep 2020 19:21:42

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:21:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c43d78ee-7693-466b-9f68-9145445131b8' User entered '96.4'	(b) (4), (b) (6) System	26 Sep 2020 19:21:42
	System	26 Sep 2020 19:21:42

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:21:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c43d78ee-7693-466b-9f68-9145445131b8' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 19:21:42
	System	26 Sep 2020 19:21:42

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:21:40', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c43d78ee-7693-466b-9f68-9145445131b8' User entered '26 Sep 2020 15:21'	(b) (4), (b) (6) System	26 Sep 2020 19:21:42
	System	26 Sep 2020 19:21:42

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 4'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:13:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '542ae936-65d6-4641-b378-4c1620abc028' User entered 'Yes (Y)'	(b) (4), (b) (6) System	27 Sep 2020 22:14:25
	System	27 Sep 2020 22:14:25

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:14:13', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '542ae936-65d6-4641-b378-4c1620abc028' User entered '98.1'	(b) (4), (b) (6) System	27 Sep 2020 22:14:25
	System	27 Sep 2020 22:14:25

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:14:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '542ae936-65d6-4641-b378-4c1620abc028'	(b) (4), (b) (6)	27 Sep 2020 22:14:25
User entered 'No (N)'	System	27 Sep 2020 22:14:25

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:14:23', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '542ae936-65d6-4641-b378-4c1620abc028' User entered '27 Sep 2020 18:14'	(b) (4), (b) (6) System	27 Sep 2020 22:14:25
	System	27 Sep 2020 22:14:25

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 5'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:56:44', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a043decf-7fa7-4126-92c8-55137723a0c8'	(b) (4), (b) (6) System	28 Sep 2020 20:58:23
User entered 'Yes (Y)'	System	28 Sep 2020 20:58:23

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:02', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a043decf-7fa7-4126-92c8-55137723a0c8' User entered '97.5'	(b) (4), (b) (6) System	28 Sep 2020 20:58:23
	System	28 Sep 2020 20:58:23

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a043decf-7fa7-4126-92c8-55137723a0c8'	(b) (4), (b) (6)	28 Sep 2020 20:58:23
User entered 'No (N)'	System	28 Sep 2020 20:58:23

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:21', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a043decf-7fa7-4126-92c8-55137723a0c8' User entered '28 Sep 2020 16:58'	(b) (4), (b) (6) System	28 Sep 2020 20:58:23
	System	28 Sep 2020 20:58:23

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 6'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:05:54', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1dbde02b-6ed2-428e-9485-21cb5a38ca8b' User entered 'Yes (Y)'	(b) (4), (b) (6) System	30 Sep 2020 03:06:35
	System	30 Sep 2020 03:06:35

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:06:16', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1dbde02b-6ed2-428e-9485-21cb5a38ca8b' User entered '96.7'	(b) (4), (b) (6) System	30 Sep 2020 03:06:35
	System	30 Sep 2020 03:06:35

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:06:25', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1dbde02b-6ed2-428e-9485-21cb5a38ca8b' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 03:06:35
	System	30 Sep 2020 03:06:35

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:06:31', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1dbde02b-6ed2-428e-9485-21cb5a38ca8b' User entered '29 Sep 2020 23:06'	(b) (4), (b) (6) System	30 Sep 2020 03:06:35
	System	30 Sep 2020 03:06:35

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 7'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:14:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c1a1cd90-58e0-4d17-98f2-c41e8c9c2630' User entered 'Yes (Y)'	(b) (4), (b) (6) System	30 Sep 2020 22:15:41
	System	30 Sep 2020 22:15:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:15:23', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c1a1cd90-58e0-4d17-98f2-c41e8c9c2630' User entered '97.9'	(b) (4), (b) (6) System	30 Sep 2020 22:15:41
	System	30 Sep 2020 22:15:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:15:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c1a1cd90-58e0-4d17-98f2-c41e8c9c2630' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 22:15:41
	System	30 Sep 2020 22:15:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:15:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c1a1cd90-58e0-4d17-98f2-c41e8c9c2630' User entered '30 Sep 2020 18:15'	(b) (4), (b) (6) System	30 Sep 2020 22:15:41
	System	30 Sep 2020 22:15:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:34:13', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9810c7ad-e087-4f82-bb04-f041e8a9cfda' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 16:34:52
	System	24 Sep 2020 16:34:52

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:34:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9810c7ad-e087-4f82-bb04-f041e8a9cfda' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 16:34:52
	System	24 Sep 2020 16:34:52

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:34:32', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9810c7ad-e087-4f82-bb04-f041e8a9cfda' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 16:34:52
	System	24 Sep 2020 16:34:52

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:34:40', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9810c7ad-e087-4f82-bb04-f041e8a9cfda' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 16:34:52
	System	24 Sep 2020 16:34:52

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:34:48', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9810c7ad-e087-4f82-bb04-f041e8a9cfda' User entered '24 Sep 2020 12:34'	(b) (4), (b) (6) System	24 Sep 2020 16:34:52
	System	24 Sep 2020 16:34:52

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 12:21'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 14:51'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:03', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b8d711d4-7be7-4954-ae9d-bd4a0dde0bf6' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 22:18:34
	System	24 Sep 2020 22:18:34

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b8d711d4-7be7-4954-ae9d-bd4a0dde0bf6' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 22:18:34
	System	24 Sep 2020 22:18:34

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:16', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b8d711d4-7be7-4954-ae9d-bd4a0dde0bf6' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 22:18:34
	System	24 Sep 2020 22:18:34

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:24', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b8d711d4-7be7-4954-ae9d-bd4a0dde0bf6' User entered 'None (1)'	(b) (4), (b) (6) System	24 Sep 2020 22:18:34
	System	24 Sep 2020 22:18:34

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:30', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b8d711d4-7be7-4954-ae9d-bd4a0dde0bf6' User entered '24 Sep 2020 18:18'	(b) (4), (b) (6) System	24 Sep 2020 22:18:34
	System	24 Sep 2020 22:18:34

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 15:46'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 2'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:08:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0367740a-22e4-4a10-bdfa-66e867b247dc'	(b) (4), (b) (6)	25 Sep 2020 22:09:08
User entered 'None (1)'	System	25 Sep 2020 22:09:08

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:08:44', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0367740a-22e4-4a10-bdfa-66e867b247dc' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:08
	System	25 Sep 2020 22:09:08

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:08:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0367740a-22e4-4a10-bdfa-66e867b247dc' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:08
	System	25 Sep 2020 22:09:08

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:08:55', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0367740a-22e4-4a10-bdfa-66e867b247dc' User entered 'None (1)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:08
	System	25 Sep 2020 22:09:08

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:06', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0367740a-22e4-4a10-bdfa-66e867b247dc' User entered '25 Sep 2020 18:09'	(b) (4), (b) (6) System	25 Sep 2020 22:09:08
	System	25 Sep 2020 22:09:08

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 3'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:21:58', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2554f3d8-db74-4451-a3c1-802aa89ecc8c' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 19:22:25
	System	26 Sep 2020 19:22:25

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:03', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2554f3d8-db74-4451-a3c1-802aa89ecc8c' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 19:22:25
	System	26 Sep 2020 19:22:25

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2554f3d8-db74-4451-a3c1-802aa89ecc8c' User entered 'No (N)'	(b) (4), (b) (6) System	26 Sep 2020 19:22:25
	System	26 Sep 2020 19:22:25

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2554f3d8-db74-4451-a3c1-802aa89ecc8c' User entered 'None (1)'	(b) (4), (b) (6) System	26 Sep 2020 19:22:25
	System	26 Sep 2020 19:22:25

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '2554f3d8-db74-4451-a3c1-802aa89ecc8c' User entered '26 Sep 2020 15:22'	(b) (4), (b) (6) System	26 Sep 2020 19:22:25
	System	26 Sep 2020 19:22:25

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 4'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:14:31', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0fac718f-54e0-4b96-a6c2-756097060b1c' User entered 'None (1)'	(b) (4), (b) (6) System	27 Sep 2020 22:14:58
	System	27 Sep 2020 22:14:58

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:14:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0fac718f-54e0-4b96-a6c2-756097060b1c' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 22:14:58
	System	27 Sep 2020 22:14:58

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:14:44', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0fac718f-54e0-4b96-a6c2-756097060b1c' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 22:14:58
	System	27 Sep 2020 22:14:58

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:14:50', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0fac718f-54e0-4b96-a6c2-756097060b1c' User entered 'None (1)'	(b) (4), (b) (6) System	27 Sep 2020 22:14:58
	System	27 Sep 2020 22:14:58

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:14:55', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '0fac718f-54e0-4b96-a6c2-756097060b1c' User entered '27 Sep 2020 18:14'	(b) (4), (b) (6) System	27 Sep 2020 22:14:58
	System	27 Sep 2020 22:14:58

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 5'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'cb5b2b6a-6f48-4237-9712-822fd70e6080' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 20:58:48
	System	28 Sep 2020 20:58:48

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:33', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'cb5b2b6a-6f48-4237-9712-822fd70e6080' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 20:58:48
	System	28 Sep 2020 20:58:48

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'cb5b2b6a-6f48-4237-9712-822fd70e6080' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 20:58:48
	System	28 Sep 2020 20:58:48

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'cb5b2b6a-6f48-4237-9712-822fd70e6080' User entered 'None (1)'	(b) (4), (b) (6) System	28 Sep 2020 20:58:48
	System	28 Sep 2020 20:58:48

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:46', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'cb5b2b6a-6f48-4237-9712-822fd70e6080' User entered '28 Sep 2020 16:58'	(b) (4), (b) (6) System	28 Sep 2020 20:58:48
	System	28 Sep 2020 20:58:48

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 6'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:06:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b9a54436-2b07-4558-8c06-c820b1d63cc4'	(b) (4), (b) (6)	30 Sep 2020 03:07:15
User entered 'None (1)'	System	30 Sep 2020 03:07:15

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:06:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b9a54436-2b07-4558-8c06-c820b1d63cc4'	(b) (4), (b) (6)	30 Sep 2020 03:07:15
User entered 'No (N)'	System	30 Sep 2020 03:07:15

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:06:56', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b9a54436-2b07-4558-8c06-c820b1d63cc4' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 03:07:15
	System	30 Sep 2020 03:07:15

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:04', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b9a54436-2b07-4558-8c06-c820b1d63cc4'	(b) (4), (b) (6) System	30 Sep 2020 03:07:15
User entered 'None (1)'	System	30 Sep 2020 03:07:15

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:07', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'b9a54436-2b07-4558-8c06-c820b1d63cc4' User entered '29 Sep 2020 23:07'	(b) (4), (b) (6) System	30 Sep 2020 03:07:15
	System	30 Sep 2020 03:07:15

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 7'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:15:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9562438a-7a9f-4bbf-a4e6-d0fe6d790965'	(b) (4), (b) (6)	30 Sep 2020 22:16:06
User entered 'None (1)'	System	30 Sep 2020 22:16:06

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:15:48', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9562438a-7a9f-4bbf-a4e6-d0fe6d790965'	(b) (4), (b) (6)	
	System	30 Sep 2020 22:16:06
User entered 'No (N)'	System	30 Sep 2020 22:16:06

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:15:54', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9562438a-7a9f-4bbf-a4e6-d0fe6d790965'	(b) (4), (b) (6)	
User entered 'No (N)'	System	30 Sep 2020 22:16:06

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:15:59', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9562438a-7a9f-4bbf-a4e6-d0fe6d790965'	(b) (4), (b) (6) System	30 Sep 2020 22:16:06
User entered 'None (1)'	System	30 Sep 2020 22:16:06

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:03', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9562438a-7a9f-4bbf-a4e6-d0fe6d790965' User entered '30 Sep 2020 18:16'	(b) (4), (b) (6) System	30 Sep 2020 22:16:06
	System	30 Sep 2020 22:16:06

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:34:57', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '96d42ec4-49f6-4cca-b3c4-26eed614a82c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 16:35:29
	System	24 Sep 2020 16:35:29

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:35:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '96d42ec4-49f6-4cca-b3c4-26eed614a82c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 16:35:29
	System	24 Sep 2020 16:35:29

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:35:04', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '96d42ec4-49f6-4cca-b3c4-26eed614a82c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 16:35:29
	System	24 Sep 2020 16:35:29

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:35:07', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '96d42ec4-49f6-4cca-b3c4-26eed614a82c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 16:35:29
	System	24 Sep 2020 16:35:29

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:35:11', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '96d42ec4-49f6-4cca-b3c4-26eed614a82c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 16:35:29
	System	24 Sep 2020 16:35:29

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:35:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '96d42ec4-49f6-4cca-b3c4-26eed614a82c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 16:35:29
	System	24 Sep 2020 16:35:29

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:35:22', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '96d42ec4-49f6-4cca-b3c4-26eed614a82c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 16:35:29
	System	24 Sep 2020 16:35:29

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T12:35:25', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '96d42ec4-49f6-4cca-b3c4-26eed614a82c' User entered '24 Sep 2020 12:35'	(b) (4), (b) (6) System	24 Sep 2020 16:35:29
	System	24 Sep 2020 16:35:29

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 12:21'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 14:51'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 1, after vaccination (at home)'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:44', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c3d815cf-415a-41f5-88ce-a3a9612b400c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 22:19:23
	System	24 Sep 2020 22:19:23

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c3d815cf-415a-41f5-88ce-a3a9612b400c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 22:19:23
	System	24 Sep 2020 22:19:23

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:53', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c3d815cf-415a-41f5-88ce-a3a9612b400c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 22:19:23
	System	24 Sep 2020 22:19:23

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:18:58', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c3d815cf-415a-41f5-88ce-a3a9612b400c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 22:19:23
	System	24 Sep 2020 22:19:23

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:19:02', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c3d815cf-415a-41f5-88ce-a3a9612b400c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 22:19:23
	System	24 Sep 2020 22:19:23

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:19:05', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c3d815cf-415a-41f5-88ce-a3a9612b400c' User entered 'None (0)'	(b) (4), (b) (6) System	24 Sep 2020 22:19:23
	System	24 Sep 2020 22:19:23

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:19:15', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c3d815cf-415a-41f5-88ce-a3a9612b400c' User entered 'No (N)'	(b) (4), (b) (6) System	24 Sep 2020 22:19:23
	System	24 Sep 2020 22:19:23

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-24T18:19:21', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c3d815cf-415a-41f5-88ce-a3a9612b400c' User entered '24 Sep 2020 18:19'	(b) (4), (b) (6) System	24 Sep 2020 22:19:23
	System	24 Sep 2020 22:19:23

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '24 Sep 2020 15:46'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 2'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1924133b-be45-470e-add9-cb2f0777acab' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:53
	System	25 Sep 2020 22:09:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1924133b-be45-470e-add9-cb2f0777acab' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:53
	System	25 Sep 2020 22:09:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:23', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1924133b-be45-470e-add9-cb2f0777acab' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:53
	System	25 Sep 2020 22:09:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1924133b-be45-470e-add9-cb2f0777acab' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:53
	System	25 Sep 2020 22:09:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:33', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1924133b-be45-470e-add9-cb2f0777acab' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:53
	System	25 Sep 2020 22:09:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:36', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1924133b-be45-470e-add9-cb2f0777acab' User entered 'None (0)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:53
	System	25 Sep 2020 22:09:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:47', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1924133b-be45-470e-add9-cb2f0777acab' User entered 'No (N)'	(b) (4), (b) (6) System	25 Sep 2020 22:09:53
	System	25 Sep 2020 22:09:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-25T18:09:51', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '1924133b-be45-470e-add9-cb2f0777acab' User entered '25 Sep 2020 18:09'	(b) (4), (b) (6) System	25 Sep 2020 22:09:53
	System	25 Sep 2020 22:09:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '25 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 3'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:30', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'aebd77a6-0a1b-4f40-b87d-369461505df2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 19:23:08
	System	26 Sep 2020 19:23:08

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'aebd77a6-0a1b-4f40-b87d-369461505df2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 19:23:08
	System	26 Sep 2020 19:23:08

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'aebd77a6-0a1b-4f40-b87d-369461505df2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 19:23:08
	System	26 Sep 2020 19:23:08

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:46', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'aebd77a6-0a1b-4f40-b87d-369461505df2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 19:23:08
	System	26 Sep 2020 19:23:08

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:50', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'aebd77a6-0a1b-4f40-b87d-369461505df2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 19:23:08
	System	26 Sep 2020 19:23:08

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:22:54', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'aebd77a6-0a1b-4f40-b87d-369461505df2' User entered 'None (0)'	(b) (4), (b) (6) System	26 Sep 2020 19:23:08
	System	26 Sep 2020 19:23:08

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:23:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'aebd77a6-0a1b-4f40-b87d-369461505df2'	(b) (4), (b) (6)	
User entered 'No (N)'	System	26 Sep 2020 19:23:08

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-26T15:23:05', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'aebd77a6-0a1b-4f40-b87d-369461505df2' User entered '26 Sep 2020 15:23'	(b) (4), (b) (6) System	26 Sep 2020 19:23:08
	System	26 Sep 2020 19:23:08

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '26 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 4'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:15:04', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dbcb238d-97a6-4f14-8f80-0b716e8250b8' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 22:15:40
	System	27 Sep 2020 22:15:40

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:15:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dbcb238d-97a6-4f14-8f80-0b716e8250b8' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 22:15:40
	System	27 Sep 2020 22:15:40

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:15:13', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dbcb238d-97a6-4f14-8f80-0b716e8250b8' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 22:15:40
	System	27 Sep 2020 22:15:40

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:15:18', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dbcb238d-97a6-4f14-8f80-0b716e8250b8' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 22:15:40
	System	27 Sep 2020 22:15:40

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:15:21', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dbcb238d-97a6-4f14-8f80-0b716e8250b8' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 22:15:40
	System	27 Sep 2020 22:15:40

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:15:25', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dbcb238d-97a6-4f14-8f80-0b716e8250b8' User entered 'None (0)'	(b) (4), (b) (6) System	27 Sep 2020 22:15:40
	System	27 Sep 2020 22:15:40

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:15:31', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dbcb238d-97a6-4f14-8f80-0b716e8250b8' User entered 'No (N)'	(b) (4), (b) (6) System	27 Sep 2020 22:15:40
	System	27 Sep 2020 22:15:40

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-27T18:15:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'dbcb238d-97a6-4f14-8f80-0b716e8250b8' User entered '27 Sep 2020 18:15'	(b) (4), (b) (6) System	27 Sep 2020 22:15:40
	System	27 Sep 2020 22:15:40

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '27 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '28 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 5'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:53', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '4ae0457c-9996-4225-b0f4-b7b94e826534' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:59:34
	System	28 Sep 2020 20:59:34

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:58:59', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '4ae0457c-9996-4225-b0f4-b7b94e826534' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:59:34
	System	28 Sep 2020 20:59:34

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:59:04', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '4ae0457c-9996-4225-b0f4-b7b94e826534' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:59:34
	System	28 Sep 2020 20:59:34

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:59:09', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '4ae0457c-9996-4225-b0f4-b7b94e826534' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:59:34
	System	28 Sep 2020 20:59:34

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:59:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '4ae0457c-9996-4225-b0f4-b7b94e826534' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:59:34
	System	28 Sep 2020 20:59:34

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:59:17', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '4ae0457c-9996-4225-b0f4-b7b94e826534' User entered 'None (0)'	(b) (4), (b) (6) System	28 Sep 2020 20:59:34
	System	28 Sep 2020 20:59:34

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:59:27', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '4ae0457c-9996-4225-b0f4-b7b94e826534' User entered 'No (N)'	(b) (4), (b) (6) System	28 Sep 2020 20:59:34
	System	28 Sep 2020 20:59:34

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-28T16:59:30', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '4ae0457c-9996-4225-b0f4-b7b94e826534' User entered '28 Sep 2020 16:59'	(b) (4), (b) (6) System	28 Sep 2020 20:59:34
	System	28 Sep 2020 20:59:34

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '28 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '29 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 6'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d12efbe-cbb5-4d9e-a6b1-cc272f0d6311' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 03:07:55
	System	30 Sep 2020 03:07:55

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:28', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d12efbe-cbb5-4d9e-a6b1-cc272f0d6311' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 03:07:55
	System	30 Sep 2020 03:07:55

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:32', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d12efbe-cbb5-4d9e-a6b1-cc272f0d6311' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 03:07:55
	System	30 Sep 2020 03:07:55

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d12efbe-cbb5-4d9e-a6b1-cc272f0d6311' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 03:07:55
	System	30 Sep 2020 03:07:55

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:39', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d12efbe-cbb5-4d9e-a6b1-cc272f0d6311' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 03:07:55
	System	30 Sep 2020 03:07:55

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:43', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d12efbe-cbb5-4d9e-a6b1-cc272f0d6311' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 03:07:55
	System	30 Sep 2020 03:07:55

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d12efbe-cbb5-4d9e-a6b1-cc272f0d6311' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 03:07:55
	System	30 Sep 2020 03:07:55

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-29T23:07:54', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9d12efbe-cbb5-4d9e-a6b1-cc272f0d6311' User entered '29 Sep 2020 23:07'	(b) (4), (b) (6) System	30 Sep 2020 03:07:55
	System	30 Sep 2020 03:07:55

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '29 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '30 Sep 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	24 Sep 2020 16:17:41
User entered 'Day 7'	System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:10', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a9ef6221-1d88-40cf-8a70-ab90e8e37164' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:16:53
	System	30 Sep 2020 22:16:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:17', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a9ef6221-1d88-40cf-8a70-ab90e8e37164' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:16:53
	System	30 Sep 2020 22:16:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:22', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a9ef6221-1d88-40cf-8a70-ab90e8e37164' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:16:53
	System	30 Sep 2020 22:16:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:26', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a9ef6221-1d88-40cf-8a70-ab90e8e37164' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:16:53
	System	30 Sep 2020 22:16:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:29', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a9ef6221-1d88-40cf-8a70-ab90e8e37164' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:16:53
	System	30 Sep 2020 22:16:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:34', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a9ef6221-1d88-40cf-8a70-ab90e8e37164' User entered 'None (0)'	(b) (4), (b) (6) System	30 Sep 2020 22:16:53
	System	30 Sep 2020 22:16:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:43', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a9ef6221-1d88-40cf-8a70-ab90e8e37164' User entered 'No (N)'	(b) (4), (b) (6) System	30 Sep 2020 22:16:53
	System	30 Sep 2020 22:16:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-09-30T18:16:50', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'a9ef6221-1d88-40cf-8a70-ab90e8e37164' User entered '30 Sep 2020 18:16'	(b) (4), (b) (6) System	30 Sep 2020 22:16:53
	System	30 Sep 2020 22:16:53

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '30 Sep 2020 12:00'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 14:47:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
User entered '01 Oct 2020 11:59'	(b) (4), (b) (6) System	24 Sep 2020 16:17:41

US3022186

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:30:21

US3022186

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '01 Oct 2020'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:30:21

US3022186

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:30:21

US3022186

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	01 Oct 2020 20:30:21

US3022186

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 20:30:46

US3022186

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	01 Oct 2020 20:30:46

US3022186

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:44:41

US3022186

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '08 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:44:41

US3022186

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:44:41

US3022186

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 17:44:41

US3022186

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:44:46

US3022186

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	16 Oct 2020 17:44:46

US3022186

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:45:01

US3022186

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '15 Oct 2020'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:45:01

US3022186

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:45:01

US3022186

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	16 Oct 2020 17:45:01

US3022186

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Oct 2020 17:45:06

US3022186

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	16 Oct 2020 17:45:06

US3022186

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:09:24

US3022186

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:09:24

US3022186

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:09:24

US3022186

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User entered 'VISIT3'	(b) (4), (b) (6) System	26 Oct 2020 20:09:24

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '26 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '11:05'	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User entered '26 Oct 2020 11:05'	(b) (4), (b) (6) System	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '37.5' C	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Oral (Oral)'	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '76'	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User entered 'bpm'	(b) (4), (b) (6) System	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '18'	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User entered 'breaths/min'	(b) (4), (b) (6) System	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '120'	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User entered 'mmHg'	(b) (4), (b) (6) System	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '80'	(b) (4), (b) (6)	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User entered 'mmHg'	(b) (4), (b) (6) System	26 Oct 2020 20:10:05

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	

US3022186

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Mar 2021 16:36:04

US3022186

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:10:17

US3022186

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:10:17

US3022186

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Oct 2020 20:10:32

US3022186

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '26 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:10:32

US3022186

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered '11:17'	(b) (4), (b) (6)	26 Oct 2020 20:10:32

US3022186

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:04
User entered '26 Oct 2020 11:17'	(b) (4), (b) (6) System	26 Oct 2020 20:10:32

US3022186

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:10:52

US3022186

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	26 Oct 2020 20:10:52

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 64'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-22T12:02:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '48e8ea47-5e93-4446-a93b-24fca7b53900'	(b) (4), (b) (6)	22 Oct 2020 16:04:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:04:30

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-22T12:02:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '48e8ea47-5e93-4446-a93b-24fca7b53900'	(b) (4), (b) (6)	22 Oct 2020 16:04:30
User entered 'No (N)'	System	22 Oct 2020 16:04:30

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-22T12:02:56', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '48e8ea47-5e93-4446-a93b-24fca7b53900'	(b) (4), (b) (6)	22 Oct 2020 16:04:30
User entered 'No (N)'	System	22 Oct 2020 16:04:30

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-22T12:03:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '48e8ea47-5e93-4446-a93b-24fca7b53900'	(b) (4), (b) (6)	22 Oct 2020 16:04:30
User entered 'Yes (Y)'	System	22 Oct 2020 16:04:30

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Please 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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-22T12:03:21', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '48e8ea47-5e93-4446-a93b-24fca7b53900'	(b) (4), (b) (6)	22 Oct 2020 16:04:30
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Oct 2020 16:04:30

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-22T12:04:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '48e8ea47-5e93-4446-a93b-24fca7b53900' User entered '22 Oct 2020 12:04:19'	(b) (4), (b) (6) System	22 Oct 2020 16:04:30
	System	22 Oct 2020 16:04:30

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 71'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-27T15:40:08', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '530c6a83-6e4e-4020-b9f0-a34068445544'	(b) (4), (b) (6)	27 Oct 2020 19:40:39
User entered 'No (N)'	System	27 Oct 2020 19:40:39

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-27T15:39:46', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '530c6a83-6e4e-4020-b9f0-a34068445544'	(b) (4), (b) (6)	27 Oct 2020 19:40:39
User entered 'No (N)'	System	27 Oct 2020 19:40:39

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-10-27T15:40:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '530c6a83-6e4e-4020-b9f0-a34068445544' User entered '27 Oct 2020 15:40:37'	(b) (4), (b) (6) System	27 Oct 2020 19:40:39
	System	27 Oct 2020 19:40:39

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 78'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-07T11:59:58', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '77a89ad7-4975-45e3-9f71-9085d058b921'	(b) (4), (b) (6)	07 Nov 2020 17:00:31
User entered 'No (N)'	System	07 Nov 2020 17:00:31

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-07T12:00:11', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '77a89ad7-4975-45e3-9f71-9085d058b921'	(b) (4), (b) (6)	07 Nov 2020 17:00:31
User entered 'No (N)'	System	07 Nov 2020 17:00:31

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-07T12:00:29', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '77a89ad7-4975-45e3-9f71-9085d058b921' User entered '07 Nov 2020 12:00:29'	(b) (4), (b) (6) System	07 Nov 2020 17:00:31
	System	07 Nov 2020 17:00:31

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:41:29
	(b) (4), (b) (6)	
Data entry locked.	System	20 Aug 2020 14:43:10
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59
Data entry locked.	System	20 Aug 2020 14:43:10
User entered 'Day 92'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
DataPoint activated (WR#5335027)	(b) (4), (b) (6)	
	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59
Data entry locked.	System	20 Aug 2020 14:43:10
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 14:43:10

US3022186

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
	(b) (4), (b) (6)	
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 23:35:59
Data entry locked.	System	20 Aug 2020 14:43:10
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 14:43:10

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-25T12:12:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '727abc97-4c39-4c85-8f90-08c9997c2ae4' User entered 'No (N)'	System	25 Nov 2020 17:13:18
	System	25 Nov 2020 17:13:18

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-25T12:12:49', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '727abc97-4c39-4c85-8f90-08c9997c2ae4' User entered 'No (N)'	System	25 Nov 2020 17:13:18

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-25T12:13:12', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '727abc97-4c39-4c85-8f90-08c9997c2ae4' User entered '25 Nov 2020 12:13:12'	System	25 Nov 2020 17:13:18
	System	25 Nov 2020 17:13:18

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-30T12:33:38', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7af3e4bc-f466-47fe-8d1b-b2242d2a4279'	System	30 Nov 2020 17:34:03
User entered 'No (N)'	System	30 Nov 2020 17:34:03

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-30T12:33:48', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7af3e4bc-f466-47fe-8d1b-b2242d2a4279'	System	30 Nov 2020 17:34:03
User entered 'No (N)'	System	30 Nov 2020 17:34:03

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-11-30T12:34:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7af3e4bc-f466-47fe-8d1b-b2242d2a4279' User entered '30 Nov 2020 12:34:00'	System	30 Nov 2020 17:34:03
	System	30 Nov 2020 17:34:03

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-07T12:40:12', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '8ea3fb96-84f3-445a-8f49-0434aeceef1e' User entered 'No (N)'	System	07 Dec 2020 17:40:44

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-07T12:40:23', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '8ea3fb96-84f3-445a-8f49-0434aeceef1e' User entered 'No (N)'	System	07 Dec 2020 17:40:44

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-07T12:40:38', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '8ea3fb96-84f3-445a-8f49-0434aeceef1e' User entered '07 Dec 2020 12:40:38'	System	07 Dec 2020 17:40:44

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-14T12:03:05', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6a80e80c-acd4-4a4c-bc25-36e82d551b51'	System	14 Dec 2020 17:03:24
User entered 'No (N)'	System	14 Dec 2020 17:03:24

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-14T12:03:13', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6a80e80c-acd4-4a4c-bc25-36e82d551b51'	System	14 Dec 2020 17:03:24
User entered 'No (N)'	System	14 Dec 2020 17:03:24

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-14T12:03:19', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '6a80e80c-acd4-4a4c-bc25-36e82d551b51' User entered '14 Dec 2020 12:03:19'	System	14 Dec 2020 17:03:24
	System	14 Dec 2020 17:03:24

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-21T12:03:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '82d816c3-427b-4c5e-8923-39b75d62883e' User entered 'No (N)'	System	21 Dec 2020 17:03:37
	System	21 Dec 2020 17:03:37

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-21T12:03:21', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '82d816c3-427b-4c5e-8923-39b75d62883e'	System	21 Dec 2020 17:03:37
User entered 'No (N)'	System	21 Dec 2020 17:03:37

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-21T12:03:31', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '82d816c3-427b-4c5e-8923-39b75d62883e' User entered '21 Dec 2020 12:03:31'	System	21 Dec 2020 17:03:37
	System	21 Dec 2020 17:03:37

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-26T10:18:51', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '5524c1c5-b1f0-45d7-b76c-d826896eb10f' User entered 'No (N)'	System	26 Dec 2020 15:19:09
	System	26 Dec 2020 15:19:09

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-26T10:18:58', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '5524c1c5-b1f0-45d7-b76c-d826896eb10f' User entered 'No (N)'	System	26 Dec 2020 15:19:09
	System	26 Dec 2020 15:19:09

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2020-12-26T10:19:07', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '5524c1c5-b1f0-45d7-b76c-d826896eb10f' User entered '26 Dec 2020 10:19:07'	System	26 Dec 2020 15:19:09
	System	26 Dec 2020 15:19:09

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-02T00:29:23', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'da786f0d-fdaa-467e-8953-07ae1478cb50'	System	02 Jan 2021 05:29:41
User entered 'No (N)'	System	02 Jan 2021 05:29:41

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-02T00:29:33', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'da786f0d-fdaa-467e-8953-07ae1478cb50'	System	02 Jan 2021 05:29:41
User entered 'No (N)'	System	02 Jan 2021 05:29:41

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-02T00:29:39', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'da786f0d-fdaa-467e-8953-07ae1478cb50'	System	02 Jan 2021 05:29:41
User entered '02 Jan 2021 00:29:39'	System	02 Jan 2021 05:29:41

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-10T16:58:25', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '16758fad-84f6-4963-ae8-c45b878d07c8' User entered 'No (N)'	System	10 Jan 2021 21:58:56
	System	10 Jan 2021 21:58:56

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-10T16:58:37', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '16758fad-84f6-4963-ae8-c45b878d07c8'	System	10 Jan 2021 21:58:56
User entered 'No (N)'	System	10 Jan 2021 21:58:56

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-10T16:58:50', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '16758fad-84f6-4963-ae8-c45b878d07c8' User entered '10 Jan 2021 16:58:50'	System	10 Jan 2021 21:58:56
	System	10 Jan 2021 21:58:56

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-18T16:00:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7c69bf43-0010-4030-9f41-ea7834ef9361'	System	18 Jan 2021 21:00:55
User entered 'No (N)'	System	18 Jan 2021 21:00:55

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-18T15:59:56', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7c69bf43-0010-4030-9f41-ea7834ef9361'	System	18 Jan 2021 21:00:55
User entered 'No (N)'	System	18 Jan 2021 21:00:55

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-18T16:00:53', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7c69bf43-0010-4030-9f41-ea7834ef9361' User entered '18 Jan 2021 16:00:53'	System	18 Jan 2021 21:00:55
	System	18 Jan 2021 21:00:55

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-23T04:56:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '33195f53-240a-4a55-acd1-ece54d536641' User entered 'No (N)'	System	23 Jan 2021 09:56:58
	System	23 Jan 2021 09:56:58

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-23T04:56:35', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '33195f53-240a-4a55-acd1-ece54d536641' User entered 'No (N)'	System	23 Jan 2021 09:56:58
	System	23 Jan 2021 09:56:58

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-23T04:56:55', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '33195f53-240a-4a55-acd1-ece54d536641' User entered '23 Jan 2021 04:56:55'	System	23 Jan 2021 09:56:58
	System	23 Jan 2021 09:56:58

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-30T15:36:54', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '84d685e4-6530-4754-9009-c70948cdb96e' User entered 'No (N)'	System	30 Jan 2021 20:37:16
	System	30 Jan 2021 20:37:16

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-30T15:37:05', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '84d685e4-6530-4754-9009-c70948cdb96e' User entered 'No (N)'	System	30 Jan 2021 20:37:16

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-01-30T15:37:14', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '84d685e4-6530-4754-9009-c70948cdb96e' User entered '30 Jan 2021 15:37:14'	System	30 Jan 2021 20:37:16
	System	30 Jan 2021 20:37:16

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-02-09T18:57:42', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7d19048e-0e99-486e-8a82-7edfd65ed43c' User entered 'No (N)'	System	09 Feb 2021 23:58:06
	System	09 Feb 2021 23:58:06

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-02-09T18:57:51', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7d19048e-0e99-486e-8a82-7edfd65ed43c' User entered 'No (N)'	System	09 Feb 2021 23:58:06

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-02-09T18:58:03', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '7d19048e-0e99-486e-8a82-7edfd65ed43c'	System	09 Feb 2021 23:58:06
User entered '09 Feb 2021 18:58:03'	System	09 Feb 2021 23:58:06

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-02-16T18:05:34', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '55e86802-39c1-4589-bcc0-a8848124efb8' User entered 'No (N)'	System	16 Feb 2021 23:10:49
	System	16 Feb 2021 23:10:49

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Have you been exposed to someone with 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 (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-02-16T18:05:43', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '55e86802-39c1-4589-bcc0-a8848124efb8' User entered 'No (N)'	System	16 Feb 2021 23:10:49
	System	16 Feb 2021 23:10:49

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (F3D0BF53-1CAE-45C3-B233-25BC5EC28AB6)', Time: '2021-02-16T18:05:52', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '55e86802-39c1-4589-bcc0-a8848124efb8' User entered '16 Feb 2021 18:05:52'	System	16 Feb 2021 23:10:49
	System	16 Feb 2021 23:10:49

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-09T12:46:41-05:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '345a0eb7-c0ef-4055-ad54-bb04e213c1f8'	System	09 Mar 2021 17:46:57
User entered 'No (N)'	System	09 Mar 2021 17:46:57

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-09T12:46:46-05:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '345a0eb7-c0ef-4055-ad54-bb04e213c1f8'	System	09 Mar 2021 17:46:57
User entered 'No (N)'	System	09 Mar 2021 17:46:57

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-09T12:46:55-05:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '345a0eb7-c0ef-4055-ad54-bb04e213c1f8'	System	09 Mar 2021 17:46:57
User entered '09 Mar 2021 12:46:55'	System	09 Mar 2021 17:46:57

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-15T17:13:11-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '00cd7871-820a-4a2a-ba3c-de7eda640d5a'	System	15 Mar 2021 21:13:33
User entered 'No (N)'	System	15 Mar 2021 21:13:33

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-15T17:13:19-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '00cd7871-820a-4a2a-ba3c-de7eda640d5a'	System	15 Mar 2021 21:13:33
User entered 'No (N)'	System	15 Mar 2021 21:13:33

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-15T17:13:30-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '00cd7871-820a-4a2a-ba3c-de7eda640d5a' User entered '15 Mar 2021 17:13:30'	System	15 Mar 2021 21:13:33
	System	15 Mar 2021 21:13:33

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-20T11:51:52-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '8c2dd365-eb75-4754-aadc-08a363cad81c'	System	20 Mar 2021 15:52:07
User entered 'No (N)'	System	20 Mar 2021 15:52:07

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-20T11:51:58-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '8c2dd365-eb75-4754-aadc-08a363cad81c'	System	20 Mar 2021 15:52:07
User entered 'No (N)'	System	20 Mar 2021 15:52:07

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-20T11:52:04-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '8c2dd365-eb75-4754-aadc-08a363cad81c' User entered '20 Mar 2021 11:52:04'	System	20 Mar 2021 15:52:07
	System	20 Mar 2021 15:52:07

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-27T09:30:29-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e7e8be52-1ab2-4c64-a9f8-adfa55892ef0' User entered 'No (N)'	System	27 Mar 2021 13:30:49
	System	27 Mar 2021 13:30:49

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-27T09:30:35-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e7e8be52-1ab2-4c64-a9f8-adfa55892ef0' User entered 'No (N)'	System	27 Mar 2021 13:30:49

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-27T09:30:46-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'e7e8be52-1ab2-4c64-a9f8-adfa55892ef0' User entered '27 Mar 2021 09:30:46'	System	27 Mar 2021 13:30:49
	System	27 Mar 2021 13:30:49

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-03T16:07:34-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9b0da048-6fda-4562-9802-4807d7d796ce'	System	03 Apr 2021 20:07:47
User entered 'No (N)'	System	03 Apr 2021 20:07:47

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-03T16:07:38-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9b0da048-6fda-4562-9802-4807d7d796ce'	System	03 Apr 2021 20:07:47
User entered 'No (N)'	System	03 Apr 2021 20:07:47

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-03T16:07:42-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '9b0da048-6fda-4562-9802-4807d7d796ce' User entered '03 Apr 2021 16:07:42'	System	03 Apr 2021 20:07:47
	System	03 Apr 2021 20:07:47

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-13T18:05:38-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'accb1166-caa2-42df-927c-22c5f1dff74a' User entered 'No (N)'	System	13 Apr 2021 22:07:53
	System	13 Apr 2021 22:07:53

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-13T18:05:43-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'accb1166-caa2-42df-927c-22c5f1dff74a' User entered 'No (N)'	System	13 Apr 2021 22:07:53
	System	13 Apr 2021 22:07:53

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-13T18:05:49-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'accb1166-caa2-42df-927c-22c5f1dff74a' User entered '13 Apr 2021 18:05:49'	System	13 Apr 2021 22:07:53
	System	13 Apr 2021 22:07:53

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-19T12:00:52-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c660d37f-7044-4700-9eb6-d21e0905c5fd'	System	19 Apr 2021 16:03:41
User entered 'No (N)'	System	19 Apr 2021 16:03:41

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-19T12:00:59-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c660d37f-7044-4700-9eb6-d21e0905c5fd' User entered 'No (N)'	System	19 Apr 2021 16:03:41

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-19T12:01:12-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: 'c660d37f-7044-4700-9eb6-d21e0905c5fd' User entered '19 Apr 2021 12:01:12'	System	19 Apr 2021 16:03:41
	System	19 Apr 2021 16:03:41

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-24T17:47:11-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '46bb5262-0f97-4960-af62-0f563d757d81'	System	24 Apr 2021 21:47:28
User entered 'No (N)'	System	24 Apr 2021 21:47:28

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-24T17:47:18-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '46bb5262-0f97-4960-af62-0f563d757d81' User entered 'No (N)'	System	24 Apr 2021 21:47:28
	System	24 Apr 2021 21:47:28

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-04-24T17:47:26-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '46bb5262-0f97-4960-af62-0f563d757d81'	System	24 Apr 2021 21:47:28
User entered '24 Apr 2021 17:47:26'	System	24 Apr 2021 21:47:28

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-05-03T12:12:25-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '36e34f7b-982d-4715-a2f5-ec0afb9b7c57'	System	03 May 2021 16:18:11
User entered 'No (N)'	System	03 May 2021 16:18:11

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

Have you been exposed to someone with 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 (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-05-03T12:12:29-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '36e34f7b-982d-4715-a2f5-ec0afb9b7c57'	System	03 May 2021 16:18:11
User entered 'No (N)'	System	03 May 2021 16:18:11

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-05-03T12:12:35-04:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '36e34f7b-982d-4715-a2f5-ec0afb9b7c57'	System	03 May 2021 16:18:11
User entered '03 May 2021 12:12:35'	System	03 May 2021 16:18:11

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:35:59

US3022186

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 14:47:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:35:59
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:35:59

US3022186

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:47:56

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-09T12:37:52-05:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '46a17d94-2962-4528-b274-23f7c697a1ff'	(b) (4), (b) (6)	
User entered 'No (N)'	System	09 Mar 2021 17:38:30

US3022186

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 14:47:56

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 09:02:56
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55EE6654-423D-4E44-AD87-AC91B5F6ED71)', Time: '2021-03-09T12:38:22-05:00', User OID: 'PatientReportedOutcome (US3022186)', ODM File OID: '46a17d94-2962-4528-b274-23f7c697a1ff' User entered '09 Mar 2021 12:38:22'	(b) (4), (b) (6) System	09 Mar 2021 17:38:30
	System	09 Mar 2021 17:38:30

US3022186

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:31:56

US3022186

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:31:56

US3022186

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:31:56

US3022186

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:17:02
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	02 Dec 2020 14:31:56

US3022186

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:17:02
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Dec 2020 14:32:14

US3022186

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 16:36:02
User entered 'I'	(b) (4), (b) (6) System	02 Dec 2020 14:32:14

US3022186

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	06 Jan 2021 16:12:12
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	06 Jan 2021 16:12:12
User opened query 'Data is required. Please complete.' (Site from System).	System	06 Jan 2021 14:29:19
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 14:29:19

US3022186

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '21 Dec 2020'	(b) (4), (b) (6)	06 Jan 2021 14:29:19

US3022186

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	06 Jan 2021 14:29:19

US3022186

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4), (b) (6)	06 Jan 2021 14:29:19

US3022186

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4), (b) (6)	06 Jan 2021 14:29:38

US3022186

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User entered 'I'	System	06 Jan 2021 14:29:38

US3022186

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:10:28

US3022186

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '22 Jan 2021'	(b) (4), (b) (6)	26 Jan 2021 14:10:28

US3022186

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	26 Jan 2021 14:10:28

US3022186

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:10:28

US3022186

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:10:32

US3022186

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User entered 'I'	System	26 Jan 2021 14:10:32

US3022186

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:00:23

US3022186

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered '23 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:00:23

US3022186

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	23 Feb 2021 21:00:23

US3022186

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:00:23

US3022186

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Feb 2021 21:00:28

US3022186

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 12:38:27
User entered 'I'	System	23 Feb 2021 21:00:28

US3022186

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User closed query 'Per Sponsor Review : Please note Visit 4 D209 and Participants Decision visit/OL-D1 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately.' (Site from DM).	(b) (4), (b) (6)	12 Apr 2021 09:41:51
Query 'Per Sponsor Review : Please note Visit 4 D209 and Participants Decision visit/OL-D1 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately.' answered with 'updated ' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 21:11:17
User opened query 'Per Sponsor Review : Please note Visit 4 D209 and Participants Decision visit/OL-D1 is done on the same date, Data should be same in Part A and Part B for these pages and all the respective pages to be completed .Vital signs if done on the same day the data should be present in both the pages and should be same .Kindly reconcile and update appropriately.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:49:29
User closed query 'Per CDM: Visit 4 Day 209 and Participants Decision visit/OL-D1 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on Participants Decision visit/OL D-1 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 16:49:29
Query 'Per CDM: Visit 4 Day 209 and Participants Decision visit/OL-D1 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on Participants Decision visit/OL D-1 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' answered with 'not required per protocol ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 14:30:45

US3022186

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Visit 4 Day 209 and Participants Decision visit/OL-D1 were performed on same day, however vital signs on Visit 4 Day 209 is not completed and on Participants Decision visit/OL D-1 is Yes. Kindly review and update as appropriate. Otherwise clarify. Thank you.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Mar 2021 21:09:09
	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 13:46:01

US3022186

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered '09 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 13:46:01

US3022186

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[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 21:32:13
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Mar 2021 13:46:01

US3022186

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User entered 'VISIT4'	(b) (4), (b) (6) System	17 Mar 2021 13:46:01

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered 'No (N)'	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Time of assessment \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered '11:05' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User entered '09 Mar 2021 11:05'	(b) (4), (b) (6)	
	System	08 Apr 2021 21:11:09
User entered empty.	System	30 Mar 2021 16:38:22

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered '36.8' C reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered '87' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User entered 'bpm'	(b) (4), (b) (6)	
	System	08 Apr 2021 21:11:09
User entered empty.	System	30 Mar 2021 16:38:22

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User entered 'breaths/min'	(b) (4), (b) (6)	
	System	08 Apr 2021 21:11:09
User entered empty.	System	30 Mar 2021 16:38:22

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered '105' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User entered 'mmHg'	(b) (4), (b) (6)	
	System	08 Apr 2021 21:11:09
User entered empty.	System	30 Mar 2021 16:38:22

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
	(b) (4)	
User entered '87' reason for change: Data Entry Error	(b) (4), (b) (6)	08 Apr 2021 21:11:09
User entered empty.	Chevon Roberts (b) (4)	30 Mar 2021 16:38:22
	(b) (4)	

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User entered 'mmHg'	(b) (4), (b) (6)	
	System	08 Apr 2021 21:11:09
User entered empty.	System	30 Mar 2021 16:38:22

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 21:32:13

US3022186

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 14:47:56

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6) (b) (4), (b) (6)	27 Apr 2021 21:32:13

US3022186

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:05:48
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Mar 2021 13:46:22

US3022186

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered '09 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 13:46:22

US3022186

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 13:46:43

US3022186

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered '09 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 13:46:43

US3022186

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered '11:24'	(b) (4), (b) (6)	17 Mar 2021 13:46:43

US3022186

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User entered '09 Mar 2021 11:24'	(b) (4), (b) (6) System	17 Mar 2021 13:46:43

US3022186

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 13:46:52

US3022186

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 21:32:13
User entered 'I'	(b) (4), (b) (6) System	17 Mar 2021 13:46:52

US3022186

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:32:57

US3022186

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:32:57

US3022186

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:32:57

US3022186

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:32:57

US3022186

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:33:01

US3022186

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:33:01

US3022186

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

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	14 Jan 2021 15:16:14

US3022186

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

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:31:00
	(b) (4), (b) (6)	
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:31:00
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '13 Jan 2021'	(b) (4), (b) (6)	14 Jan 2021 15:16:14
	(b) (4), (b) (6)	

US3022186

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

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[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 19:51:54
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	14 Jan 2021 15:16:14

US3022186

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

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User entered 'UNBLND_DECIDE'	(b) (4), (b) (6) System	14 Jan 2021 15:16:14

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

Date of updated informed consent (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:36:22
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:32:39
	(b) (4), (b) (6)	
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:32:39
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered '13 Jan 2021'	(b) (4), (b) (6)	24 Feb 2021 14:46:04

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[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 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered '0' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:14:46

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 14:46:04

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 13:14:46

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

Date of unblinding (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:36:22
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:32:39
	(b) (4), (b) (6)	
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:32:39
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered '13 Jan 2021'	(b) (4), (b) (6)	24 Feb 2021 14:46:04

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	24 Feb 2021 14:46:04

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:46:04

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	24 Feb 2021 14:46:04

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:46:04

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User entered '1'	(b) (4), (b) (6) System	24 Feb 2021 14:46:04

US3022186

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

Form: Unblinding

Generated On: 09 Jun 2021 14:47:56

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User entered 'I'	(b) (4), (b) (6) System	24 Feb 2021 14:46:04

US3022186

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered empty.	System	24 Feb 2021 14:46:47
DataPoint set to visible.	System	24 Feb 2021 14:46:04

US3022186

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered empty.	System	24 Feb 2021 14:46:47
DataPoint set to visible.	System	24 Feb 2021 14:46:04

US3022186

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

US3022186

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 14:33:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered '11:05' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered '09 Mar 2021 11:05'	System	19 Mar 2021 14:33:26
User entered empty.	System	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered '36.8' C reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

US3022186

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered '87' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'bpm'	System	19 Mar 2021 14:33:26
User entered empty.	System	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	19 Mar 2021 14:33:26
User entered empty.	System	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered '105' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'mmHg'	System	19 Mar 2021 14:33:26
User entered empty.	System	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4), (b) (6)	
User entered '87' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'mmHg'	System	19 Mar 2021 14:33:26
User entered empty.	System	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered empty.	System	24 Feb 2021 14:46:47
DataPoint set to visible.	System	24 Feb 2021 14:46:04

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6) (b) (4), (b) (6)	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

US3022186

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:05:48
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:33:51
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
User signature succeeded.	(b) (4) Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User entered '12:32' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered '09 Mar 2021 12:32'	System	19 Mar 2021 14:33:51
User entered empty.	System	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User entered '36.9' C reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User entered '77' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'bpm'	System	19 Mar 2021 14:33:51
User entered empty.	System	24 Feb 2021 14:46:47

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User entered '14' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'breaths/min'	System	19 Mar 2021 14:33:51
User entered empty.	System	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User entered '133' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'mmHg'	System	19 Mar 2021 14:33:51
User entered empty.	System	24 Feb 2021 14:46:47

US3022186

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4), (b) (6)	
User entered '88' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:33:51
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:47
	(b) (4), (b) (6)	

US3022186

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'mmHg'	System	19 Mar 2021 14:33:51
User entered empty.	System	24 Feb 2021 14:46:47

US3022186

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:34:01
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 14:34:01
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 14:46:55

US3022186

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

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:34:01
	(b) (4), (b) (6)	
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:34:01
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:46:55
	(b) (4), (b) (6)	

US3022186

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:34:26
	(b) (4), (b) (6)	
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 14:34:26
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 14:47:11

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	25 Mar 2021 23:05:48
Signature has been broken.	(b) (4) (b) (4), (b) (6)	19 Mar 2021 14:34:26
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:34:26
User signature succeeded.	(b) (4) Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered 'Physician withheld dose due to Adverse Event (PHYSICIAN AE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:47:11

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:47:11

US3022186

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'mRNA-1273'	System	19 Mar 2021 14:34:26
User entered empty.	System	24 Feb 2021 14:47:11
DataPoint set to visible.	System	24 Feb 2021 14:46:04

US3022186

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:34:26
	(b) (4), (b) (6)	
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 14:34:26
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:47:11

US3022186

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:34:26
	(b) (4), (b) (6)	
User entered '12:00' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:34:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:47:11
	(b) (4), (b) (6)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered '09 Mar 2021 12:00'	System	19 Mar 2021 14:34:26
User entered empty.	System	24 Feb 2021 14:47:11

US3022186

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:34:26
	(b) (4), (b) (6)	
User entered 'Left Arm (LEFT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:34:26
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:47:11
	(b) (4), (b) (6)	

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'ONCE'	System	19 Mar 2021 14:34:26
User entered empty.	System	24 Feb 2021 14:47:11

US3022186

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

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'INTRAMUSCULAR'	System	19 Mar 2021 14:34:26
User entered empty.	System	24 Feb 2021 14:47:11

US3022186

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 14:47:24

US3022186

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	23 Apr 2021 17:39:19
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 17:39:19
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	23 Apr 2021 17:37:52
Signature has been broken.	(b) (4), (b) (6)	23 Apr 2021 17:37:52
User entered '13 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 17:37:52
User closed query 'Per GCL lab Recon: Per Preclarus report, this "OL-D1" Immuno sample is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 10:26:18
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
Query 'Per GCL lab Recon: Per Preclarus report, this "OL-D1" Immuno sample is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' answered with 'Subject was out on delay due to AE. This is the day that they were drawn at new visit.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:48:12
User closed query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	19 Mar 2021 14:34:53
User closed query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	19 Mar 2021 14:34:53
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:34:53

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User entered '09 Mar 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 14:34:53
User opened query 'The Collection Date is before the Date of Updated Informed Consent. Please review and reconcile.' (Site from System).	System	19 Mar 2021 14:32:39
User opened query 'The Collection Date is prior to the Participant Decision Visit Date. Please review and reconcile.' (Site from System).	System	19 Mar 2021 14:31:00
User opened query 'Per GCL lab Recon: Per Preclarus report, this "OL-D1" Immuno sample is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 11:00:31
Query 'Per GCL lab Recon: Per Preclarus report, this OL-D1 Immuno sample is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' canceled (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 11:00:21
User opened query 'Per GCL lab Recon: Per Preclarus report, this OL-D1 Immuno sample is missing in PPD GCL. Please kindly confirm if the sample has been collected and shipped, and if shipped kindly provide barcode #, Accession #, AWB #, Shipping date to track the missing sample. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 10:59:18
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered '13 Jan 2021'	(b) (4), (b) (6)	24 Feb 2021 14:47:24

US3022186

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Mar 2021 14:34:53
	(b) (4), (b) (6)	
User entered '11:24' reason for change: Data Entry Error	(b) (4)	19 Mar 2021 14:34:53
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered '13:49'	(b) (4), (b) (6)	24 Feb 2021 14:47:24
	(b) (4), (b) (6)	

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 14:47:56

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered '09 Mar 2021 11:24'	System	23 Apr 2021 17:39:19
User entered '13 Jan 2021 11:24'	System	23 Apr 2021 17:37:52
User entered '09 Mar 2021 11:24'	System	19 Mar 2021 14:34:53
User entered '13 Jan 2021 13:49'	System	24 Feb 2021 14:47:24

US3022186

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:47:51

US3022186

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab Sample: Re-Query: Per response, if OL-1 visit was conducted on 09-Mar-2021, please update date of collection. OL-1 Swab Sample appears to be still missing from Preclarus reports. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 03:45:22
User closed query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted. However, sample dated 13-Jan-2021 for OL-1 is still missing in PPD Central lab. Kindly keep this query in "Open" state until the missing issue is resolved or else until you can provide Accession and Shipment details. Thank you.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 03:45:22
Query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted. However, sample dated 13-Jan-2021 for OL-1 is still missing in PPD Central lab. Kindly keep this query in "Open" state until the missing issue is resolved or else until you can provide Accession and Shipment details. Thank you.' answered with 'OL-1 visit was 9-Mar-2021 which is in PPD ' (Site from DM).	(b) (4), (b) (6)	20 Apr 2021 16:05:06
User opened query 'Per GCL Lab Reconciliation: Nasopharyngeal Swab: Re-Query: Response noted. However, sample dated 13-Jan-2021 for OL-1 is still missing in PPD Central lab. Kindly keep this query in "Open" state until the missing issue is resolved or else until you can provide Accession and Shipment details. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:54:08
User closed query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 06:54:08
Query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' answered with 'This has been forwarded to the lab for clarification.' (Site from DM).	Chevon Roberts (b) (4) (b) (4)	12 Apr 2021 20:44:40

US3022186

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Swab: Re-query: Response noted, However please provide both Accession number, Requisition kit id and the shipment tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:02:18
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 13JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	31 Mar 2021 07:02:18
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 13JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' answered with 'Per Lab waiting for PPD to resolve ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 17:16:55
User closed query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	19 Mar 2021 14:36:22
User opened query 'The Collection Date is before the Date of Updated Informed consent. Please review and reconcile.' (Site from System).	System	19 Mar 2021 14:32:39
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 13JAN2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Mar 2021 10:33:35
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:47:51

US3022186

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:56

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered '13:55'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:47:51

US3022186

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 14:47:56

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '13 Jan 2021 13:55'	System	24 Feb 2021 14:47:51

US3022186

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

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 16:33:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 16:33:27
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 14:47:58

US3022186

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

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 19:51:54
	(b) (4), (b) (6)	
User entered 'I'	System	19 Apr 2021 16:33:27
User entered empty.	System	24 Feb 2021 14:47:58

US3022186

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:33:49

US3022186

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '16 Mar 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:33:49

US3022186

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:33:49

US3022186

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 14:47:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:33:49

US3022186

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:33:52

US3022186

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:33:52

US3022186

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:33:52
DataPoint set to visible.	System	19 Apr 2021 16:33:52

US3022186

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:34:11

US3022186

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:34:11

US3022186

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:34:11

US3022186

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 14:47:56

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD29'	System	19 Apr 2021 16:34:11

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '11:08'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User entered '19 Apr 2021 11:08'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '37.1' C	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '74'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '132'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '82'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 14:47:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Timepoint](#)

Audit	User	Time (GMT)
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '12:19'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User entered '19 Apr 2021 12:19'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '37.0' C	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '70'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '16'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '138'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '86'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 14:47:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	19 Apr 2021 16:35:51

US3022186

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:36:06

US3022186

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 14:47:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:36:06

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:36:26

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[If No, reason not given](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:36:26

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:36:26

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
User entered 'mRNA-1273'	System	19 Apr 2021 16:36:26
DataPoint set to visible.	System	19 Apr 2021 16:33:52

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '19 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:36:26

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	19 Apr 2021 16:36:33
User entered '11:38' reason for change: Data Entry Error	System	19 Apr 2021 16:36:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	19 Apr 2021 16:36:26
User entered '38:' (non-conformant).	System	19 Apr 2021 16:36:26
	(b) (4), (b) (6)	

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '19 Apr 2021 11:38'	System	19 Apr 2021 16:36:33
User entered '19 Apr 2021 38:' (non-conformant).	System	19 Apr 2021 16:36:26

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:36:26

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
User entered 'ONCE'	System	19 Apr 2021 16:36:26

US3022186

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 14:47:56

[What was the route of administration for the study treatment?](#)

Audit	User	Time (GMT)
User entered 'INTRAMUSCULAR'	System	19 Apr 2021 16:36:26

US3022186

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:36:37

US3022186

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 14:47:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 16:36:37

US3022186

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 14:47:56

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:33
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:07:18
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Oct 2020 12:46:59
	(b) (4)	

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 17:54:30
	(b) (4), (b) (6)	
User entered	(b) (4), (b) (6)	16 Oct 2020 17:54:23
'USA-US051-2020-mRNA-1273-P301000009'	(b) (4), (b) (6)	

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	16 Oct 2020 12:48:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 12:48:28
Data point term sent to Coder	System	16 Oct 2020 12:47:51
User entered 'Syncope'	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 12:47:35

US3022186

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 12:48:38
User entered 'No (N)' reason for change: Data Entry Error	System	16 Oct 2020 12:48:38
User opened query 'Data is required. Please complete.' (Site from System).	Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
User entered empty.	(b) (4)	
	System	16 Oct 2020 12:47:35
	Shanice Bennett (b) (4)	16 Oct 2020 12:47:35
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'Per DM CLR: Please review the dates of this AE as and event of Fall is not expected to have a duration of more than a single date. Please review and update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	10 Nov 2020 08:49:46
Query 'Per DM CLR: Please review the dates of this AE as and event of Fall is not expected to have a duration of more than a single date. Please review and update as appropriate or provide clarification.' answered with 'updated' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:55:07
User entered '11 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:54:46
User opened query 'Per DM CLR: Please review the dates of this AE as and event of Fall is not expected to have a duration of more than a single date. Please review and update as appropriate or provide clarification.' (Site from DM).	(b) (4), (b) (6)	24 Oct 2020 21:05:08
User entered '14 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:48:38
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 12:47:35

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	16 Oct 2020 12:48:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 12:48:38
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:47:35
User entered empty.	Shanice Bennett (b) (4)	16 Oct 2020 12:47:35
	(b) (4)	

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	
System		16 Oct 2020 12:48:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 12:48:38
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:47:35
User entered empty.	Shanice Bennett (b) (4)	16 Oct 2020 12:47:35
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) System	16 Oct 2020 12:48:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 12:48:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:48:38
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:47:35
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) System	16 Oct 2020 12:48:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 12:48:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:48:38
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:47:35
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User closed query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 16:15:56
	(b) (4), (b) (6)	
Query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4)	04 Nov 2020 21:55:54
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	04 Nov 2020 21:55:35
	(b) (4)	
User opened query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 11:24:39
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:48:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 12:48:38
User entered 'None (NONE)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:47:35
User entered empty.	Shanice Bennett (b) (4)	16 Oct 2020 12:47:35
	(b) (4)	

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None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 12:11:51
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 12:11:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 13:13:34
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 12:48:38
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	16 Oct 2020 12:47:35
User entered '0'	Shanice Bennett (b) (4)	16 Oct 2020 12:47:35
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'If no conmed taken, please unmark. ' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 21:36:51
Query 'If no conmed taken, please unmark. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	12 Apr 2021 20:19:28
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:19:12
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:19:12
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User opened query 'If no conmed taken, please unmark. ' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 13:41:16
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 12:11:51
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 12:11:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 16:02:49
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 16:02:39
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 14:27:52
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'no med taken ' (Site from DM).	Shanice Bennett (b) (4)	19 Nov 2020 23:35:17
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	19 Nov 2020 13:13:34
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:46:50
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 12:48:38
User entered '0'	Shanice Bennett (b) (4)	16 Oct 2020 12:47:35

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 12:11:51
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	07 Apr 2021 12:11:51
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	16 Oct 2020 12:47:35
	(b) (4)	

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6) System	16 Oct 2020 12:48:50
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Oct 2020 12:48:50
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:48:50
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Oct 2020 12:47:35
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:47:35

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'PV Query: Please consider reporting AE Dehydration.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:16:06
User closed query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc)' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:16:04
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:16:02
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:15:59
Query 'PV Query: Please consider reporting AE Dehydration.' answered with 'updated' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:57:46
Query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc)' answered with 'Unknown' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:57:13
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:57:04
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'No applicable ' (Site from Safety).	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:56:55
User opened query 'PV Query: Please consider reporting AE Dehydration.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 11:25:38
User opened query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc)' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 11:25:24

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 11:25:04
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	26 Oct 2020 11:24:53
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Oct 2020 12:50:29
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	16 Oct 2020 12:50:29
User entered 'Subject reported having fallen twice and went to the Emergency Department in Statesboro. He was informed that he was dehydrated and that's why he fainted and fell.' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 12:50:29
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Oct 2020 12:48:38
User entered empty.	Shanice Bennett (b) (4)	16 Oct 2020 12:47:35

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 12:48:38

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Oct 2020 12:47:35

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Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 12:48:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 17:54:30
	(b) (4), (b) (6)	
User entered	System	16 Oct 2020 17:54:11
'USA-US051-2020-mRNA-1273-P301000009'		
User entered 'New'	(b) (4), (b) (6)	16 Oct 2020 17:54:11
	(b) (4), (b) (6)	

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Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Fracture rib - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 13:17:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	16 Oct 2020 13:17:23
Data point term sent to Coder	System	16 Oct 2020 13:16:10
User entered 'Fracture Ribs'	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 21:41:45
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 15:22:06
User entered 'Yes (Y)'	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered with 'There is no end date in the chart for this AE' (Site from System).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 13:00:37
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 19:06:42
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 21:41:45
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	16 Oct 2020 15:22:06
User entered '14 Oct 2020' reason for change: Data Entry Error	System	16 Oct 2020 15:22:06
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Oct 2020 15:21:46
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' canceled (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 14:25:57
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:55:44
User entered empty.	System	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 15:21:46
User entered 'Grade 3/Severe (Grade 3/Severe)'	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 15:21:46
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	16 Oct 2020 13:16:25
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	16 Oct 2020 13:15:25
User entered 'No (N)'	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		16 Oct 2020 15:23:29
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		16 Oct 2020 15:23:29
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Oct 2020 15:21:46
User entered '1' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 15:21:46
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 13:16:25
	(b) (4)	
User entered '1'	Shanice Bennett (b) (4)	16 Oct 2020 13:15:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	16 Oct 2020 15:21:46
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	16 Oct 2020 13:16:25
User entered '11 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '14 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	16 Oct 2020 15:21:46
User entered empty; reason for change Data Entry Error	(b) (4) Shanice Bennett (b) (4)	16 Oct 2020 13:16:25
User entered '14 Oct 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 16:04:00
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 15:23:29
	(b) (4)	
User entered empty; reason for change Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 13:16:25
	(b) (4)	
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Oct 2020 13:15:25
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	16 Nov 2020 23:36:46
Query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'UPDATED' (Site from Safety).	Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 22:17:19
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 22:17:10
User opened query 'PV Query: As the last dose of study drug was given on 24 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:54:57
User entered 'None (NONE)'	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '1'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'PV Query: Query response to final outcome was "confirmed". Please clarify your response, for the event "fracture ribs". Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	24 Nov 2020 16:03:12
Query 'PV Query: Query response to final outcome was "confirmed". Please clarify your response, for the event "fracture ribs". Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' answered with 'This does not have a final outcome' (Site from Safety).	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 19:08:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Per Query Resolution	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 19:08:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	Morgan Deal (b) (4) (b) (4)	23 Nov 2020 19:05:35
User opened query 'PV Query: Query response to final outcome was "confirmed". Please clarify your response, for the event "fracture ribs". Please provide the final event outcome, when available. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	20 Nov 2020 18:53:57
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	16 Nov 2020 23:36:54
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' answered with 'CONFIRMED' (Site from Safety).	Chevon Roberts (b) (4) (b) (4)	13 Nov 2020 22:18:08

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Folder: Adverse Events

Form: Adverse Events (2)

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[Outcome](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:55:25
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Nov 2020 21:41:45
User closed query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	16 Oct 2020 15:23:29
User opened query 'Specify sequelae is provided, but Outcome is not Recovered/Resolved with Sequelae. Please correct.' (Site from System).	System	16 Oct 2020 15:21:46
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	16 Oct 2020 15:21:46
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Shanice Bennett (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4)	16 Oct 2020 15:23:29
User entered 'due to SAE Syncope' reason for change: Data Entry Error	(b) (4) Shanice Bennett (b) (4)	16 Oct 2020 15:21:46
User entered empty.	(b) (4) Shanice Bennett (b) (4)	16 Oct 2020 13:15:25
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	(b) (4), (b) (6) System	16 Oct 2020 15:23:29
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	16 Oct 2020 15:23:29
User entered 'DUE TO SAE SYNCOPE' reason for change: Data Entry Error	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 15:23:29
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	16 Oct 2020 15:21:46
User entered empty.	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 14:47:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 15:21:46
User entered '0'	System	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 13:15:25

US3022186

Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Oct 2020 13:15:25

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Folder: Adverse Events

Form: Adverse Events (3)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:04
	(b) (4), (b) (6)	
User entered	(b) (4), (b) (6)	05 Nov 2020 16:16:27
'USA-US051-2020-mRNA-1273-P301000009'	(b) (4), (b) (6)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	(b) (4), (b) (6)	
	Coder Import (b) (4)	04 Nov 2020 22:00:30
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Nov 2020 22:00:30
	(b) (4)	
Data point term sent to Coder	System	04 Nov 2020 21:59:58
User entered 'Dehydration'	Shanice Bennett (b) (4)	04 Nov 2020 21:59:02
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '14 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Grade 4 (Grade 4)' reason for change: Data Entry Error	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	09 Nov 2020 21:41:11
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	
User closed query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	04 Nov 2020 21:59:17
User entered 'Yes (Y)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	04 Nov 2020 21:59:17
	(b) (4)	
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	04 Nov 2020 21:59:02
User entered 'No (N)'	Shanice Bennett (b) (4)	04 Nov 2020 21:59:02
	(b) (4)	

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '1'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '14 Oct 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:30
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'Per DM CLR: Please review if there are treatments given for this SAE as treatments are expected. If treatments were given for this event, please update to record accordingly. Otherwise, clarify why no treatment was needed.' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	23 Nov 2020 14:28:25
Query 'Per DM CLR: Please review if there are treatments given for this SAE as treatments are expected. If treatments were given for this event, please update to record accordingly. Otherwise, clarify why no treatment was needed.' answered with 'this is correct' (Site from DM).	Shanice Bennett (b) (4) (b) (4)	19 Nov 2020 23:35:37
User opened query 'Per DM CLR: Please review if there are treatments given for this SAE as treatments are expected. If treatments were given for this event, please update to record accordingly. Otherwise, clarify why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	19 Nov 2020 08:46:30
User entered 'I'	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 15:43:01
Query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' answered with 'Discharge summary sent' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:52:38
User opened query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:34:52
User closed query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Etiology would be the cause of the dehydration, so the cause cannot be the same term as the event. If unknown, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 15:29:49
Query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Etiology would be the cause of the dehydration, so the cause cannot be the same term as the event. If unknown, please state so in your response.' answered with 'unknown' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 18:05:49
User opened query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Etiology would be the cause of the dehydration, so the cause cannot be the same term as the event. If unknown, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	24 Feb 2021 15:39:24

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per progress note on 14Oct20, there is no specific reason for dehydration, but there is a specific reason for broken ribs (syncope). Please confirm and update.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 16:46:26
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	14 Jan 2021 16:46:24
	(b) (4), (b) (6)	
Query 'Per progress note on 14Oct20, there is no specific reason for dehydration, but there is a specific reason for broken ribs (syncope). Please confirm and update.' answered with 'this is correct' (Site from CRA).	(b) (4), (b) (6)	10 Dec 2020 21:08:35
User opened query 'Per progress note on 14Oct20, there is no specific reason for dehydration, but there is a specific reason for broken ribs (syncope). Please confirm and update.' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 15:14:04
	(b) (4), (b) (6)	
	(b) (4), (b) (6)	10 Dec 2020 14:58:52
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User closed query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Response: Unknown' (Site from Safety).	(b) (4), (b) (6)	17 Nov 2020 13:21:43
Query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Response: Unknown' answered with 'DEHYDRATION' (Site from Safety).	Chevon Roberts (b) (4)	13 Nov 2020 22:18:43
	(b) (4)	
User opened query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Response: Unknown' (Site from Safety).	(b) (4), (b) (6)	13 Nov 2020 16:56:45
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Nov 2020 22:00:12
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	04 Nov 2020 22:00:12
User entered 'DUE TO SAE SYNCOPED' reason for change: Data Entry Error	Shanice Bennett (b) (4)	04 Nov 2020 22:00:12
	(b) (4)	

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	04 Nov 2020 21:59:17
User entered empty.	Shanice Bennett (b) (4) (b) (4)	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Nov 2020 21:59:17
User entered '0'	System	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 14:47:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	04 Nov 2020 21:59:02

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:04
	(b) (4), (b) (6)	
User entered	System	19 Nov 2020 20:07:15
'USA-US051-2020-mRNA-1273-P301000012'		
User entered 'New'	(b) (4), (b) (6)	19 Nov 2020 20:07:15

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Total fluid volume decreased, PT: Dehydration, LLT: Dehydration - version MedDRA\\23.0.	(b) (4), (b) (6) Coder Import (b) (4) (b) (4)	18 Nov 2020 16:32:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:32:47
Data point term sent to Coder	System	18 Nov 2020 16:32:13
User entered 'DEHYDRATION'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Nov 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:14:59
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Subject is coming in on Monday 12/21/2020 to sign medical release so that we can send them.' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 17:57:34
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:23:39
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '13 Nov 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '1'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Nov 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '13 Nov 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

None

Audit	User	Time (GMT)
User closed query 'Per CDM CLR re-query: Response noted; however please confirm if con-med is listed for treatment of this condition. If yes Kindly update con-med and AE eCRF as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:42:36
Query 'Per CDM CLR re-query: Response noted; however please confirm if con-med is listed for treatment of this condition. If yes Kindly update con-med and AE eCRF as appropriate. Thank you.' answered with 'nothing listed for dehydration' (Site from DM).	(b) (4), (b) (6)	18 Mar 2021 18:06:53
User opened query 'Per CDM CLR re-query: Response noted; however please confirm if con-med is listed for treatment of this condition. If yes Kindly update con-med and AE eCRF as appropriate. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 05:59:18
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected in a subject hospitalized. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	24 Feb 2021 05:56:47
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected in a subject hospitalized. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'waiting for medical records ' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 13:45:43
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected in a subject hospitalized. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:07:55
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'I'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:33:20
User closed query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:50:09
Query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:29:41
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User opened query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 19:32:27
User closed query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:42:01

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' answered with 'records sent ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 17:35:19
User opened query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:23:11
User closed query 'PV Query: Medical records still have not been received. Please re-send discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed. ' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:21:46
Query 'PV Query: Medical records still have not been received. Please re-send discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed. ' answered with 'medical records were requested on 10/16/2020' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:02:16
User opened query 'PV Query: Medical records still have not been received. Please re-send discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed. ' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:17:27
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	28 Dec 2020 21:21:03

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'still waiting for medical records ' (Site from Safety).	(b) (4), (b) (6)	23 Dec 2020 13:42:07
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:26:36
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 16:15:10
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'We are waiting on medical records ' (Site from Safety).	(b) (4), (b) (6)	17 Dec 2020 17:57:48
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 17:23:07
DataPoint Un-verified.	(b) (4), (b) (6)	10 Dec 2020 16:35:57
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Etiology would be the cause of the dehydration, so the cause cannot be the same term as the event. If unknown, please state so in your response.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6) (b) (4), (b) (6)	01 Dec 2020 13:05:56
Query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Etiology would be the cause of the dehydration, so the cause cannot be the same term as the event. If unknown, please state so in your response.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	30 Nov 2020 15:06:43
User entered 'diarrhea' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Nov 2020 15:06:37

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (4)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: What was etiology of dehydration (i.e. poor oral intake, diarrhea, etc). Etiology would be the cause of the dehydration, so the cause cannot be the same term as the event. If unknown, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 18:40:51
User entered 'DIARRHEA CAUSED DEHYDRATION'	Shanice Bennett (b) (4)	18 Nov 2020 16:31:46

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 14:47:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 16:31:46

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:04
	(b) (4), (b) (6)	
User entered	(b) (4), (b) (6)	19 Nov 2020 20:08:14
'USA-US051-2020-mRNA-1273-P301000012'		

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User closed query 'Per DM CLR: Please confirm if this AE is a worsening of Diarrhoea noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6) (b) (4), (b) (6)	08 Dec 2020 06:57:17
Query 'Per DM CLR: Please confirm if this AE is a worsening of Diarrhoea noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' answered with 'no worsening of diarrhea. ' (Site from DM).	(b) (4), (b) (6)	07 Dec 2020 18:08:53
User opened query 'Per DM CLR: Please confirm if this AE is a worsening of Diarrhoea noted in the MH eCRF. If yes, please update the AE term to reflect the term 'worsening or exacerbation' and ensure any Con Med indications are updated if required. Otherwise, If this is a duplicate please confirm if it meets the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	05 Dec 2020 11:10:41
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Diarrhoea (excl infective), PT: Diarrhoea, LLT: Diarrhea - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:35:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	18 Nov 2020 16:35:46
Data point term sent to Coder	System	18 Nov 2020 16:34:17
User entered 'DIARRHEA'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Nov 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 17:47:04
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:47:04
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	18 Nov 2020 16:33:19
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 17:47:04
User entered '13 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	11 Dec 2020 17:47:04
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the event end date for diarrhea (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:41:09
Query 'PV Query: Please provide the event end date for diarrhea (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'subject still having a little diarrhea' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:34:41
User opened query 'PV Query: Please provide the event end date for diarrhea (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:28:10
User entered empty.	Shanice Bennett (b) (4)	18 Nov 2020 16:33:19
	(b) (4)	

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date for diarrhea (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:26:00
User opened query 'PV Query: Please provide the event end date for diarrhea (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:33:30
User entered empty.	System	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Grade 4 (Grade 4)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Yes (Y)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '1'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '11 Nov 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '13 Nov 2020'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'No (N)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '1'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

US3022186

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered '0'	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User closed query 'PV Query: Please provide the final event outcome for the event diarrhea, when available. ' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 20:03:29
Query 'PV Query: Please provide the final event outcome for the event diarrhea, when available. ' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 17:47:10
DataPoint Un-verified.	(b) (4), (b) (6)	11 Dec 2020 17:47:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4), (b) (6)	11 Dec 2020 17:47:04
Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	
User opened query 'PV Query: Please provide the final event outcome for the event diarrhea, when available. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:32:07
User closed query 'PV Query: Please provide the final event outcome for the event diarrhea, when available.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:41:26
Query 'PV Query: Please provide the final event outcome for the event diarrhea, when available.' answered with 'this is correct ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:35:00
User opened query 'PV Query: Please provide the final event outcome for the event diarrhea, when available.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:27:24
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Shanice Bennett (b) (4)	18 Nov 2020 16:33:19
	(b) (4)	

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6) (b) (4), (b) (6)	10 Dec 2020 14:57:24
User entered empty.	(b) (4), (b) (6) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	14 Apr 2021 18:33:45
User closed query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:50:17
Query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:30:18
User opened query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	23 Mar 2021 19:32:35
User closed query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:42:30
Query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' answered with 'records sent ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 17:35:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Medical records still have not been received. Please RE-SEND discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 19:23:00
User closed query 'PV Query: Medical records still have not been received. Please re-send discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	08 Feb 2021 17:23:49
Query 'PV Query: Medical records still have not been received. Please re-send discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' answered with 'medical records sent on 10/16/2020' (Site from Safety).	(b) (4), (b) (6)	05 Feb 2021 17:02:38
User opened query 'PV Query: Medical records still have not been received. Please re-send discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query open until discharge summary is emailed or faxed.' (Site from Safety).	(b) (4), (b) (6)	05 Jan 2021 15:42:46
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Jan 2021 16:57:05
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'RECORDS HAVE BEEN SENT PER COORDINATOR' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 13:28:07

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Folder: Adverse Events

Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Dec 2020 21:26:12
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	16 Dec 2020 16:35:14
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' answered with 'records sent' (Site from Safety).	(b) (4), (b) (6)	15 Dec 2020 20:49:31
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 20:03:46
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 20:03:37
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' answered with 'pending medical records' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 17:47:47
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' answered with 'subject did not get tested' (Site from Safety).	(b) (4), (b) (6)	11 Dec 2020 17:47:24
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:57:24
	(b) (4), (b) (6)	

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Form: Adverse Events (5)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:32:56
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:32:29
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so. ' (Site from Safety).	(b) (4), (b) (6)	08 Dec 2020 13:31:52
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6) (b) (4), (b) (6)	03 Dec 2020 12:30:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Will fax' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 14:34:56
User closed query 'PV Query: What is the underlying etiology/cause of the chronic diarrhea (e.g. Crohn's disease, ulcerative colitis, celiac disease, irritable bowel syndrome, etc)' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:41:40
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:41:36
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:41:32

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: What is the underlying etiology/cause of the chronic diarrhea (e.g. Crohn's disease, ulcerative colitis, celiac disease, irritable bowel syndrome, etc)' answered with 'waiting on records ' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:35:47
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'records requested' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:35:23
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'records requested' (Site from Safety).	(b) (4), (b) (6)	24 Nov 2020 20:35:16
User opened query 'PV Query: What is the underlying etiology/cause of the chronic diarrhea (e.g. Crohn's disease, ulcerative colitis, celiac disease, irritable bowel syndrome, etc)' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:28:56
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:27:53
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:27:41
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	23 Nov 2020 21:27:13
User entered 'HOSPITALIZATION DUE TO DIARRHEA THAT CASUED DEHYDRATION'	Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 14:47:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Nov 2020 16:33:19

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:11
	(b) (4), (b) (6)	
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal inflammatory conditions, HLT: Colitis (excl infective), PT: Colitis microscopic, LLT: Lymphocytic colitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 17:11:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Jan 2021 17:11:13
Data point term sent to Coder	System	26 Jan 2021 14:11:51
User entered 'LYMPHOCYTIS COLITIS'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:13
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:16
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:18
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:25
	(b) (4), (b) (6)	
User entered '16 Dec 2020'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:28
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:39
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:44
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:46
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:48
	(b) (4), (b) (6)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:50
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:47
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:55
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:44:58
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:02
	(b) (4), (b) (6)	
User entered 'None (NONE)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:07
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM, DM CLR RQ: Site's response noted; however, colonoscopy (con proc #3) is recorded for 11 Dec 2020 which is prior to the start date of this AE (16 Dec 2020). Please review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 11:06:50
Query 'Per CDM, DM CLR RQ: Site's response noted; however, colonoscopy (con proc #3) is recorded for 11 Dec 2020 which is prior to the start date of this AE (16 Dec 2020). Please review and reconcile, else clarify. ' answered with 'updated' (Site from DM).	Chevon Roberts (b) (4)	20 Apr 2021 19:55:35
DataPoint Un-verified.	Chevon Roberts (b) (4)	20 Apr 2021 19:54:55
User entered '0' reason for change: Data Entry Error	Chevon Roberts (b) (4)	20 Apr 2021 19:54:55
User opened query 'Per CDM, DM CLR RQ: Site's response noted; however, colonoscopy (con proc #3) is recorded for 11 Dec 2020 which is prior to the start date of this AE (16 Dec 2020). Please review and reconcile, else clarify. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:05:50
User closed query 'Per CDM, DM CLR re-query: Response noted; however, this field is to be ticked when there is a procedure to address the condition (Action taken). Please review if this field should be unticked or another procedure added. Thank you. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 14:05:50
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:05
Query 'Per CDM, DM CLR re-query: Response noted; however, this field is to be ticked when there is a procedure to address the condition (Action taken). Please review if this field should be unticked or another procedure added. Thank you. ' answered with 'This was a portion for the colonoscopy ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 14:56:32

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per CDM, DM CLR re-query: Response noted; however, this field is to be ticked when there is a procedure to address the condition (Action taken). Please review if this field should be unticked or another procedure added. Thank you. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:27:56
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 13:27:56
Query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' answered with 'This is the finding of the CT of the abdomen ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 17:40:04
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however there is no Concomitant Procedure or Non-Drug Therapy (i.e., Medical Treatment procedure and not diagnostic procedure) recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 00:30:08
User entered 'I'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:38
	(b) (4), (b) (6)	
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:36
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:33
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 14:47:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Jan 2021 14:11:35

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:56
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 15:19:47
User entered 'USA-US051-2021-mRNA-1273-P301000006'	(b) (4), (b) (6)	25 Feb 2021 15:19:40

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:45:51
	(b) (4), (b) (6)	
User closed query 'For coding purposes, please clarify AE term BASAL CELL CARCINOMA OF THE LUNG. Is this Basal cell carcinoma metastatic, Squamous cell carcinoma of lung or something else. Please update the term with your response.' (Site from Coder).	(b) (4), (b) (6)	22 Mar 2021 10:37:21
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Respiratory and mediastinal neoplasms malignant and unspecified, HLT: Non-small cell neoplasms malignant of the respiratory tract cell type specified, PT: Non-small cell lung cancer, LLT: Non-small cell lung cancer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 10:36:46
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Mar 2021 10:36:46
Query 'For coding purposes, please clarify AE term BASAL CELL CARCINOMA OF THE LUNG. Is this Basal cell carcinoma metastatic, Squamous cell carcinoma of lung or something else. Please update the term with your response.' answered with 'updated' (Site from Coder).	(b) (4), (b) (6)	19 Mar 2021 17:53:08
Data point term sent to Coder	System	19 Mar 2021 17:51:09
DataPoint Un-verified.	(b) (4), (b) (6)	19 Mar 2021 17:50:12
Coding entries removed.	(b) (4), (b) (6)	19 Mar 2021 17:50:12
User entered 'non- small CELL CARCINOMA OF THE LUNG' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:50:12
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Skin neoplasms malignant and unspecified, HLT: Skin neoplasms malignant and unspecified (excl melanoma), PT: Basal cell carcinoma, LLT: Basal cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 13:01:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 13:01:26

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'For coding purposes, please clarify AE term BASAL CELL CARCINOMA OF THE LUNG. Is this Basal cell carcinoma metastatic, Squamous cell carcinoma of lung or something else. Please update the term with your response.' (Site from Coder).	(b) (4), (b) (6)	28 Feb 2021 13:00:11
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:58:12
	(b) (4), (b) (6)	
Data point term sent to Coder	System	24 Feb 2021 14:44:12
User entered 'BASAL CELL CARCINOMA OF THE LUNG'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:58:10
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:58:14
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:58:33
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:29:33
Query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.'	(b) (4), (b) (6)	12 Apr 2021 20:28:55
answered with 'Per patient this is correct' (Site from Safety).		
User closed query 'Please ascertain start date of condition and update. It did not start on 14Jan2021.' (Site from CRA).	(b) (4), (b) (6)	29 Mar 2021 18:35:48
	(b) (4), (b) (6)	
User opened query 'PV Query: Per protocol, SAE start date should be when the subject began to experience symptoms, not when the event became serious. Please consider updating event start date to onset date of symptoms. If not updating the start date, please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:29:37
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:46:00
	(b) (4), (b) (6)	
Query 'Please ascertain start date of condition and update. It did not start on 14Jan2021.' answered with 'this is the day the subject was admitted to the hospital' (Site from CRA).	(b) (4), (b) (6)	19 Mar 2021 17:53:24
User opened query 'Please ascertain start date of condition and update. It did not start on 14Jan2021.' (Site from CRA).	(b) (4), (b) (6)	24 Feb 2021 17:59:38
	(b) (4), (b) (6)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:08:37
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:08:34
	(b) (4), (b) (6)	
User entered 'No (N)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:08:21
	(b) (4), (b) (6)	
User entered '14 Jan 2021'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:08:32
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:07:48
	(b) (4), (b) (6)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:07:46
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

US3022186

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the hospital discharge date for the event basal cell carcinoma of the lung.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:41:34
User closed query 'PV Query: Please provide the hospital admission date for the event basal cell carcinoma of the lung.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 18:41:33
Query 'PV Query: Please provide the hospital discharge date for the event basal cell carcinoma of the lung.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 17:53:35
Query 'PV Query: Please provide the hospital admission date for the event basal cell carcinoma of the lung.' answered with 'updated ' (Site from Safety).	(b) (4), (b) (6)	19 Mar 2021 17:53:31
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		19 Mar 2021 17:50:12
Query 'Requires inpatient or prolongation of existing System Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).		19 Mar 2021 17:50:12
User opened query 'PV Query: Please provide the hospital discharge date for the event basal cell carcinoma of the lung.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:57:41
User opened query 'PV Query: Please provide the hospital admission date for the event basal cell carcinoma of the lung.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 20:57:25
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:34
	(b) (4), (b) (6)	
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	24 Feb 2021 14:43:14
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:46:29
	(b) (4), (b) (6)	
User entered '14 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:50:12
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:29:39
Query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' answered with 'Subject had to be watched for a couple of days after the intensive surgery ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:35:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User opened query 'PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:26:17
User entered '25 Jan 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:50:12
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:46:38
	(b) (4), (b) (6)	
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Mar 2021 17:53:56
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		19 Mar 2021 17:53:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:53:56
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	19 Mar 2021 17:53:01
User entered 'Unknown (UNK)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:53:01
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:50:12
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Number of Days in ICU

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User closed query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	23 Mar 2021 13:31:10
Query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' answered with 'We were unable to find the amount of time the subject was in the ICU' (Site from System).	(b) (4), (b) (6)	19 Mar 2021 17:54:28
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	19 Mar 2021 17:53:56
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Mar 2021 17:53:01
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Mar 2021 17:53:01
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Mar 2021 17:50:12
User entered 'unk' (non-conformant).	(b) (4), (b) (6)	19 Mar 2021 17:50:12
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:48
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:50
	(b) (4), (b) (6)	
User entered 'Not Related (NOT RELATED)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:00
	(b) (4), (b) (6)	
User closed query 'PV Query: As the last dose of [study drug] was given on 24 Sep 2020, please update the action taken with [study drug] from none to not applicable. If study drug has been given since [date], please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:29:43
Query 'PV Query: As the last dose of [study drug] was given on 24 Sep 2020, please update the action taken with [study drug] from none to not applicable. If study drug has been given since [date], please update the EDC accordingly.' answered with 'updated' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:36:16
DataPoint Un-verified.	(b) (4), (b) (6)	12 Apr 2021 20:34:58
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	12 Apr 2021 20:34:58
User opened query 'PV Query: As the last dose of [study drug] was given on 24 Sep 2020, please update the action taken with [study drug] from none to not applicable. If study drug has been given since [date], please update the EDC accordingly.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:22:19
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:52
	(b) (4), (b) (6)	
User entered 'None (NONE)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered '0'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 14:47:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:58:00
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:58:02
	(b) (4), (b) (6)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:48:53
	(b) (4), (b) (6)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 20:10:45
User closed query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 20:10:35
Query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' answered with 'we are unaware of any risk factors' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 20:00:32
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'lobectomy was done for this ae' (Site from Safety).	Chevon Roberts (b) (4)	20 Apr 2021 19:59:00
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Apr 2021 20:29:48
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'it is unstated in the medical records ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 20:38:07
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:27:31

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Folder: Adverse Events

Form: Adverse Events (8)

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide any underlying or pre-disposing risk factors associated with the event.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:25:11
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Mar 2021 15:24:01
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 19:47:17
	(b) (4), (b) (6)	
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Mar 2021 18:13:12
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Mar 2021 18:13:12
User entered 'He had a planned surgery, he was successfully taken to the recovery room and ICU for an unknown amount of days. He seemed to be doing well and progressing successfully over the next few days. He was discharged on the 25th of January.'	(b) (4), (b) (6)	19 Mar 2021 18:13:12
reason for change: Data Entry Error		
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	24 Feb 2021 14:43:14
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:43:14

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Folder: Adverse Events

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Feb 2021 14:43:14

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Folder: Adverse Events

Form: Adverse Events (8)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Mar 2021 17:53:56
User entered '0'	System	19 Mar 2021 17:53:01
User entered '1'	System	19 Mar 2021 17:50:12

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:33
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User closed query 'Per ETRTR: Please confirm whether medication was dosed for Syncope, otherwise state so within SAE "Syncope" page, thanks.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	15 Nov 2020 20:51:19
Query 'Per ETRTR: Please confirm whether medication was dosed for Syncope, otherwise state so within SAE "Syncope" page, thanks.' answered with 'No medication ' (Site from CRA).	(b) (4), (b) (6)	13 Nov 2020 23:13:31
User opened query 'Per ETRTR: Please confirm whether medication was dosed for Syncope, otherwise state so within SAE "Syncope" page, thanks.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 20:45:57
User entered 'Yes (Y)'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:03:27

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE HYDROCHLORIDE, PRODUCTSYNONYM: PROZAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 17:07:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 17:07:20
Data point term sent to Coder	System	20 Aug 2020 17:05:02
User entered 'prozac'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'anxiety'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '20'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'mg (mg)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'once daily (QD)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Oral (ORAL)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Stella Yoon (b) (4)	20 Aug 2020 17:06:25
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	20 Aug 2020 17:04:16
User entered 'un UNK 2018'	Stella Yoon (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '0'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'No (N)'	(b) (4) Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:04:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:04:16

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 17:04:16

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 17:04:16

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: VALSARTAN, PRODUCTSYNONYM: DIOVAN - version WHODrug-Global-B3\\202003.	(b) (4) Coders Import (b) (4) (b) (4)	20 Aug 2020 17:06:32
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coders Import (b) (4) (b) (4)	20 Aug 2020 17:06:32
Data point term sent to Coder User entered 'diovane'	System Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:06:08 20 Aug 2020 17:06:05

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'hypertension'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '320'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'mg (mg)'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'once daily (QD)'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'Oral (ORAL)'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4) (b) (4)	23 Feb 2021 18:15:17
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 05:48:43
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'ongoing' (Site from System).	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:06:21
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	20 Aug 2020 17:06:05
User entered 'un UNK 2000'	Stella Yoon (b) (4) (b) (4)	20 Aug 2020 17:06:05

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '0'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Dec 2020 19:44:59
	(b) (4)	
User entered 'Yes (Y)'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '22 Oct 2020' reason for change: Data Entry Error	Shanice Bennett (b) (4)	09 Dec 2020 19:44:59
	(b) (4)	
User entered empty.	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'No (N)'	Stella Yoon (b) (4)	20 Aug 2020 17:06:05
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User entered '1'	(b) (4), (b) (6) System	20 Aug 2020 17:06:05

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User entered '1'	(b) (4), (b) (6) System	20 Aug 2020 17:06:05

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User entered '804 (804)'	(b) (4), (b) (6) System	20 Aug 2020 17:06:05

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Oct 2020 15:45:23
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Oct 2020 15:45:23
Data point term sent to Coder	System	16 Oct 2020 12:52:53
User entered 'Metronidazole'	Shanice Bennett (b) (4) (b) (4)	16 Oct 2020 12:52:17

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:02
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:04
	(b) (4), (b) (6)	
User entered 'broken Ribs'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:06
	(b) (4), (b) (6)	
User entered '500'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:08
	(b) (4), (b) (6)	
User entered 'mg (mg)'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:14
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:16
	(b) (4), (b) (6)	
User entered 'twice daily (BID)'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:18
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:20
	(b) (4), (b) (6)	
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:22
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:24
	(b) (4), (b) (6)	
User entered '14 Oct 2020'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:27
	(b) (4), (b) (6)	
User entered '0'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:29
	(b) (4), (b) (6)	
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 AE eCRF as appropriate.	(b) (4), (b) (6)	17 Nov 2020 08:17:24
' (Site from DM).		
Query 'Per DM CLR:Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update AE eCRF as appropriate.	(b) (4), (b) (6)	13 Nov 2020 23:12:04
' answered with 'No still ongoing ' (Site from DM).		
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 AE eCRF as appropriate.	(b) (4), (b) (6)	03 Nov 2020 21:05:37
' (Site from DM).		
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:31
	(b) (4), (b) (6)	
User entered empty.	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 17:04:32
	(b) (4), (b) (6)	
User entered 'No (N)'	Shanice Bennett (b) (4)	16 Oct 2020 12:52:17
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Oct 2020 12:52:17

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 12:52:17

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Oct 2020 12:52:17

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 20:15:40
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	26 Oct 2020 20:15:40
	(b) (4)	
Data point term sent to Coder	System	26 Oct 2020 20:14:50
User entered 'influenza vaccine'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:01:50
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 14:36:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Dec 2020 14:36:51
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 03:19:29
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'influenza prophylaxis'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '0.5'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'mL (mL)'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'once (ONCE)'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '10 Oct 2020'	(b) (4) (b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '10 Oct 2020'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User entered empty.	(b) (4), (b) (6) System	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User entered empty.	(b) (4), (b) (6) System	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 10:49:46
User entered empty.	(b) (4), (b) (6) System	26 Oct 2020 20:14:15

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User coded data point as ATC: ANTIPARASITIC PRODUCTS, INSECTICIDES AND REPELLENTS, ATC: ANTIPROTOZOALS, ATC: AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES, ATC: OTHER AGENTS AGAINST AMOEBIASIS AND OTHER PROTOZOAL DISEASES, PRODUCT: NITAZOXANIDE, PRODUCTSYNONYM: ALINIA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:35:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Nov 2020 16:35:46
Data point term sent to Coder	System	18 Nov 2020 16:35:18
User entered 'ALINIA'	Shanice Bennett (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'DIARRHEA'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '500'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'mg (mg)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'once daily (QD)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Oral (ORAL)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '11 Nov 2020'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '0'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'No (N)'	(b) (4) Shanice Bennett (b) (4) (b) (4)	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	18 Nov 2020 16:34:33

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: OTHER MINERAL PRODUCTS, PRODUCT: ASCORBIC ACID;CHROMIUM;SELENIUM;VANADYL SULFATE, PRODUCTSYNONYM: DIAVAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Dec 2020 19:46:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Dec 2020 19:46:56
Data point term sent to Coder	System	09 Dec 2020 19:45:44
User entered 'Diavan'	Shanice Bennett (b) (4) (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Hypertension'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.	(b) (4), (b) (6)	16 Feb 2021 02:21:44
' (Site from DM).		
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.	(b) (4), (b) (6)	29 Jan 2021 15:54:31
' answered with 'this is correct' (Site from DM).		
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.	(b) (4), (b) (6)	29 Jan 2021 08:00:52
' (Site from DM).		
User entered '180'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'mg (mg)'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'once daily (QD)'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Oral (ORAL)'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) Shanice Bennett (b) (4)	09 Dec 2020 19:45:39
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '22 Oct 2020'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '0'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 16:37:14
	(b) (4), (b) (6)	
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 16:37:14
	(b) (4)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered 'Yes (Y)'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	19 Apr 2021 16:37:14
User entered '01 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 16:37:14
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered empty.	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39
	(b) (4)	

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'No (N)'	Shanice Bennett (b) (4)	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User entered '1'	(b) (4), (b) (6) System	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User entered '1'	(b) (4), (b) (6) System	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 21:53:41
User entered '804 (804)'	(b) (4), (b) (6) System	09 Dec 2020 19:45:39

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIDIARRHEALS, INTESTINAL ANTIINFLAMMATORY/ANTIINFECTIVE AGENTS, ATC: INTESTINAL ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS ACTING LOCALLY, PRODUCT: BUDESONIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	27 Jan 2021 00:08:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Jan 2021 00:08:53
Data point term sent to Coder	System	26 Jan 2021 14:13:51
User entered 'BUDESONDIE'	(b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'LYMPHOCYTIC COLITIS'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '3'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '0'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	26 Jan 2021 14:13:47

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OXAZOL, THIAZINE, AND TRIAZINE DERIVATIVES, PRODUCT: CHLORMEZANONE;IBUPROFEN;METAMIZOL E SODIUM, PRODUCTSYNONYM: DIORAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Apr 2021 16:39:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Apr 2021 16:39:31
Data point term sent to Coder	System	19 Apr 2021 16:39:07
User entered 'dioran'	(b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'hypertension'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '320'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

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

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 14:47:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Apr 2021 16:38:20

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 14:47:56

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:03:33
	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:59:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Feb 2021 21:00:40

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:47:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:00:09
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered '14 Jan 2021'	(b) (4), (b) (6)	23 Feb 2021 21:01:05

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:47:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:00:11
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered 'lung lobectomy'	(b) (4), (b) (6)	23 Feb 2021 21:01:05

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:00:12
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	23 Feb 2021 21:01:05

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 14:47:56

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 18:00:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	24 Feb 2021 00:08:31
User entered empty.	(b) (4), (b) (6)	23 Feb 2021 21:01:05

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:47:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:31:16
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered '12 Nov 2020'	(b) (4), (b) (6)	24 Feb 2021 14:44:32

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:47:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:31:16
User signature succeeded.	(b) (4), (b) (6)	
	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered 'CT OF ABDOMEN'	(b) (4), (b) (6)	24 Feb 2021 14:44:32

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:31:16
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:44:32

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 14:47:56

[If indication is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:31:16
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:44:32

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:47:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:31:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered '11 Dec 2020'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:44:50

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:47:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:31:17
User signature succeeded.	(b) (4), (b) (6) Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered 'COLONOSCOPY'	(b) (4) (b) (4), (b) (6)	24 Feb 2021 14:44:50

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:47:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:31:17
User closed query 'Per CDM DM CLR Re-query: Per response however for Syncope Concomitant procedure is not ticked, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Apr 2021 06:11:05
Query 'Per CDM DM CLR Re-query: Per response however for Syncope Concomitant procedure is not ticked, kindly review and amend as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	07 Apr 2021 12:12:50
User opened query 'Per CDM DM CLR Re-query: Per response however for Syncope Concomitant procedure is not ticked, kindly review and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:50:43
User closed query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 02:49:05
Query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' answered with 'This is associated with syncope ' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 14:27:25
User opened query 'Per DM CLR: Indication = Adverse Event, however, there is no corresponding medical condition recorded for this procedure in the AE eCRF page. Please reconcile and update to record the condition as appropriate, otherwise clarify.' (Site from DM).	(b) (4), (b) (6)	17 Mar 2021 17:57:06
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	24 Feb 2021 14:44:50

US3022186

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 14:47:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 17:31:17
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	24 Feb 2021 14:44:50

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Death

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:16:35
	(b) (4), (b) (6)	
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:16:35
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
User entered '16/Oct/2020 14:01'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:16:35
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	16 Oct 2020 18:01:10
	(b) (4), (b) (6)	

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:16:35
	(b) (4), (b) (6)	
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
User entered '05/Nov/2020 11:16'	System	05 Nov 2020 16:16:44

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 14:02:30
DataPoint Verified.	(b) (4), (b) (6)	09 Nov 2020 20:07:10
User entered 'I'	(b) (4), (b) (6)	05 Nov 2020 16:16:44
	(b) (4), (b) (6)	

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:16:35
	(b) (4), (b) (6)	
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '10/Nov/2020 14:02'	(b) (4) System	10 Nov 2020 14:02:46

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:56

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 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	16 Nov 2020 23:37:34
User entered 'I'	(b) (4), (b) (6)	10 Nov 2020 14:02:46

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:16:35
	(b) (4), (b) (6)	
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '16/Nov/2020 23:37'	(b) (4) System	16 Nov 2020 23:37:46

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:47:56

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 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	20 Nov 2020 20:35:18
User entered 'I'	(b) (4), (b) (6)	16 Nov 2020 23:37:46

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:16:35
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '20/Nov/2020 20:35'	(b) (4) System	20 Nov 2020 20:35:30

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:47:56

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 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 16:03:32
User entered 'I'	(b) (4), (b) (6)	20 Nov 2020 20:35:30

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:16:35
	(b) (4), (b) (6)	
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '24/Nov/2020 11:03'	(b) (4) System	24 Nov 2020 16:03:45

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 14:47:56

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 16:25:53
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 18:36:52
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'I'	(b) (4), (b) (6)	24 Nov 2020 16:03:45

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 16:16:35
	(b) (4), (b) (6)	
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
User entered '07/Apr/2021 13:37'	(b) (4) System	07 Apr 2021 18:37:03

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 14:47:56

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 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
User entered 'I'	(b) (4), (b) (6)	07 Apr 2021 18:37:03

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered		
'USA-US051-2020-MRNA-1273-P301000009'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'Yes (Y)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'No (N)'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Paul'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Bradley'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '340 Eisenhower Dr.'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered 'Savannah'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6)	16 Oct 2020 18:01:05
	(b) (4), (b) (6)	
User entered 'GA'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	16 Oct 2020 18:01:05
User entered '31406'	System	16 Oct 2020 17:54:11

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Nov 2020 20:07:10
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	05 Nov 2020 16:16:35
User entered 'US'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	13 Apr 2021 20:16:49
User entered '7'	System	07 Apr 2021 18:37:03
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '6'	System	24 Nov 2020 16:03:45
User entered '5'	System	20 Nov 2020 20:35:30
User entered '4'	System	16 Nov 2020 23:37:46
User entered '3'	System	10 Nov 2020 14:02:46
User entered '2'	System	05 Nov 2020 16:16:44
User entered '1'	System	16 Oct 2020 18:01:10

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
User entered '13/Apr/2021 16:16'	(b) (4) System	13 Apr 2021 20:16:49

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000009

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 14:47:56

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 16:25:53
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 20:16:49

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered		
'USA-US051-2020-MRNA-1273-P301000012'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Paul'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Bradley'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Savannah'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'GA'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '31406'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:29
	(b) (4), (b) (6)	
User entered 'US'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:43:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '3'	System	11 Dec 2020 20:05:01
User entered '2'	System	01 Dec 2020 13:06:35
User entered '1'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered		
'USA-US051-2020-MRNA-1273-P301000012'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Paul'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Bradley'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Savannah'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'GA'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '31406'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:29
	(b) (4), (b) (6)	
User entered 'US'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:43:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '3'	System	11 Dec 2020 20:05:01
User entered '2'	System	01 Dec 2020 13:06:35
User entered '1'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
User entered '19/Nov/2020 15:08'	(b) (4), (b) (6) System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:29
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered		
'USA-US051-2020-MRNA-1273-P301000012'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Paul'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Bradley'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Savannah'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'GA'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '31406'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:29
	(b) (4), (b) (6)	
User entered 'US'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:43:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '3'	System	11 Dec 2020 20:05:01
User entered '2'	System	01 Dec 2020 13:06:35
User entered '1'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
User entered '01/Dec/2020 08:06'	(b) (4), (b) (6) System	01 Dec 2020 13:06:35

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	11 Dec 2020 20:04:44
DataPoint Verified.	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
User entered 'I'	(b) (4), (b) (6)	01 Dec 2020 13:06:35
	(b) (4), (b) (6)	

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered		
'USA-US051-2020-MRNA-1273-P301000012'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Paul'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Bradley'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Savannah'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'GA'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '31406'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:29
	(b) (4), (b) (6)	
User entered 'US'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:43:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '3'	System	11 Dec 2020 20:05:01
User entered '2'	System	01 Dec 2020 13:06:35
User entered '1'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '11/Dec/2020 12:04'	(b) (4) System	11 Dec 2020 20:05:01

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:56

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 16:26:14
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:43:00
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'I'	(b) (4), (b) (6)	11 Dec 2020 20:05:01

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered		
'USA-US051-2020-MRNA-1273-P301000012'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Yes (Y)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'No (N)'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Paul'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Dec 2020 14:36:25
Reviewed for Safety.	(b) (4), (b) (6) (b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Bradley'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '340 Eisenhower Dr.'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'Savannah'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered 'GA'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	19 Nov 2020 20:08:31
User entered '31406'	System	19 Nov 2020 20:07:15

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Dec 2020 14:36:25
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	01 Dec 2020 13:06:29
	(b) (4), (b) (6)	
User entered 'US'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '4'	System	22 Mar 2021 18:43:13
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '3'	System	11 Dec 2020 20:05:01
User entered '2'	System	01 Dec 2020 13:06:35
User entered '1'	System	19 Nov 2020 20:08:40

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
User entered '22/Mar/2021 13:43'	(b) (4) System	22 Mar 2021 18:43:13

US3022186

Folder: SAE USA-US051-2020-MRNA-1273-P301000012

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:47:56

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 16:26:14
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 18:43:13

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'USA-US051-2021-MRNA-1273-P301000006'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:35:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Paul'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Bradley'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '340 Eisenhower Dr.'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Savannah'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'GA'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '31406'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 15:19:58
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'US'	(b) (4) System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 13:32:29
User entered '4'	System	13 Apr 2021 20:28:20
User entered '3'	System	22 Mar 2021 18:44:09
Signature has been broken.	System	25 Feb 2021 15:20:17
User entered '2'	System	25 Feb 2021 15:20:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '1'	System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'USA-US051-2021-MRNA-1273-P301000006'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:35:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Paul'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Bradley'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: Street

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '340 Eisenhower Dr.'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Savannah'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: [State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'GA'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '31406'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 15:19:58
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'US'	(b) (4) System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 13:32:29
User entered '4'	System	13 Apr 2021 20:28:20
User entered '3'	System	22 Mar 2021 18:44:09
Signature has been broken.	System	25 Feb 2021 15:20:17
User entered '2'	System	25 Feb 2021 15:20:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '1'	System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered '22/Feb/2021 13:58'	(b) (4) System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 14:47:56

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 16:26:27
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 15:19:58
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'I'	(b) (4), (b) (6)	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'USA-US051-2021-MRNA-1273-P301000006'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:35:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Paul'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Bradley'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '340 Eisenhower Dr.'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Savannah'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'GA'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '31406'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 15:19:58
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'US'	(b) (4) System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 13:32:29
User entered '4'	System	13 Apr 2021 20:28:20
User entered '3'	System	22 Mar 2021 18:44:09
Signature has been broken.	System	25 Feb 2021 15:20:17
User entered '2'	System	25 Feb 2021 15:20:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '1'	System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered '25/Feb/2021 10:20'	(b) (4) System	25 Feb 2021 15:20:17

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 14:47:56

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 16:26:27
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 18:43:54
User signature succeeded.	Paul Bradley (b) (4)	05 Mar 2021 23:00:00
User entered 'I'	(b) (4), (b) (6)	25 Feb 2021 15:20:17

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'USA-US051-2021-MRNA-1273-P301000006'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:35:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Paul'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Bradley'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '340 Eisenhower Dr.'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Savannah'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'GA'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '31406'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 15:19:58
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'US'	(b) (4) System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 13:32:29
User entered '4'	System	13 Apr 2021 20:28:20
User entered '3'	System	22 Mar 2021 18:44:09
Signature has been broken.	System	25 Feb 2021 15:20:17
User entered '2'	System	25 Feb 2021 15:20:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '1'	System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
User entered '22/Mar/2021 13:44'	(b) (4) System	22 Mar 2021 18:44:09

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 14:47:56

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 16:26:27
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	13 Apr 2021 20:28:04
User signature succeeded.	Paul Bradley (b) (4)	25 Mar 2021 23:05:48
User entered 'I'	(b) (4), (b) (6)	22 Mar 2021 18:44:09

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'USA-US051-2021-MRNA-1273-P301000006'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:35:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Paul'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Bradley'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '340 Eisenhower Dr.'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Savannah'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'GA'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '31406'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 15:19:58
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'US'	(b) (4) System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 13:32:29
User entered '4'	System	13 Apr 2021 20:28:20
User entered '3'	System	22 Mar 2021 18:44:09
Signature has been broken.	System	25 Feb 2021 15:20:17
User entered '2'	System	25 Feb 2021 15:20:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '1'	System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:26:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
User entered '13/Apr/2021 20:28'	(b) (4) System	13 Apr 2021 20:28:20

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 14:47:56

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 16:26:27
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	13 Apr 2021 22:18:28
User entered 'I'	(b) (4), (b) (6)	13 Apr 2021 20:28:20

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:38
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'USA-US051-2021-MRNA-1273-P301000006'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:40
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 13:35:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:43
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:46
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Yes (Y)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:47
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:49
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:50
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'No (N)'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:54
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Paul'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:55
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Bradley'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:57
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '340 Eisenhower Dr.'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:56:59
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'Savannah'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

Site Address: State

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:02
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered 'GA'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:06
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
Reviewed for Safety.	(b) (4), (b) (6)	22 Feb 2021 18:58:34
User entered '31406'	System	22 Feb 2021 18:57:54

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[Investigator Country](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 15:19:58
DataPoint Verified.	(b) (4), (b) (6)	24 Feb 2021 17:57:05
	(b) (4), (b) (6)	
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
User entered 'US'	(b) (4) System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 14:47:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	21 Apr 2021 13:32:29
User entered '4'	System	13 Apr 2021 20:28:20
User entered '3'	System	22 Mar 2021 18:44:09
Signature has been broken.	System	25 Feb 2021 15:20:17
User entered '2'	System	25 Feb 2021 15:20:17
User signature succeeded.	Paul Bradley (b) (4)	23 Feb 2021 18:15:17
	(b) (4)	
User entered '1'	System	22 Feb 2021 18:58:45

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:47:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered '21/Apr/2021 06:32'	(b) (4) System	21 Apr 2021 13:32:29

US3022186

Folder: SAE USA-US051-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 14:47:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Paul Bradley (b) (4)	28 Apr 2021 11:17:54
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:32:29