

US3292259 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:28:39

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US3292259

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 21:29:50

Generated On: 09 Jun 2021 16:28:39

[Participant ID](#)

US3292259

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

US3292259

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

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) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

Date of Birth (MMM yyyy)	(b) (6) 1970
Age	50
Age Units	YEARS
Age (Derived)	50
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	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) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

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) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	LOW BACK SURGERY
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1998
Start Year (derived)	1998
Stop Month and Year (derived)	JAN 1998
Stop Year (derived)	1998

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	LOW BACK SURGERY
Start date (dd MMM yyyy)	UN UNK 1999
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 1999
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1999
Start Year (derived)	1999
Stop Month and Year (derived)	JAN 1999
Stop Year (derived)	1999

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	VENTRAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2011
Start Year (derived)	2011
Stop Month and Year (derived)	JAN 2011
Stop Year (derived)	2011

US3292259

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	VENTRAL HERNIA REPAIR
Start date (dd MMM yyyy)	UN UNK 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 UNK 2017
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2017
Start Year (derived)	2017
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	VENTRAL HERNIA
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	JAN 2017
Stop Year (derived)	2017

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	DIABETES TYPE II
Start date (dd MMM yyyy)	UN NOV 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)	NOV 2019
Start Year (derived)	2019
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	LOW BACK PAIN
Start date (dd MMM yyyy)	UN UNK 1998
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 1998
Start Year (derived)	1998
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	HEAD CONTUSION
Start date (dd MMM yyyy)	15 MAY 2020
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)	15 MAY 2020
Stop date completely unknown	False
Start Month and Year (derived)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	MAY 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	HEADACHES SECONDARY TO HEAD CONTUSION
Start date (dd MMM yyyy)	15 MAY 2020
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)	MAY 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Condition	HYPERCHOLESTEROLEMIA
Start date (dd MMM yyyy)	15 AUG 2020
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)	AUG 2020
Start Year (derived)	2020
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

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)	14:40 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 14:40
Height (xxx.x)	160.0 cm
Weight (xxx.x)	86.2 kg
BMI (xxx.x)	33.67188 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

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: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 21:29:53

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Date of assessment (dd MMM yyyy) 20 AUG 2020

Is the participant of childbearing potential? Yes ☒
No ☐

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

If Partner medically sterile or Other, specify _____
If Surgically sterile, date of surgery (dd MMM yyyy) _____
Date of surgery unknown False
If Post-menopausal, date of last menstruation (dd MMM yyyy) _____
Date of last menstruation unknown False

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Folder: Screening

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (dd MMM yyyy)	20 AUG 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 21:29:53

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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	False
Specify	

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

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) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

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

What was the participant's randomization number? 144351

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) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	15:52 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 15:52
Temperature (xxx.x)	036.6 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	071 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	075 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

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)	17:30 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 17:30
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="checkbox"/> Axillary <input type="checkbox"/> Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	79 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was the pregnancy test performed? Yes ☐
No ☒

Date of test (dd MMM yyyy) _____

Test performed Urine ☐
Serum ☐

Result Positive ☐
Negative ☐

Was FSH sample collected? Yes ☐
No ☐

Collection date _____

Collection time _____

Collection date and time (derived) _____

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

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

Treatment Date and Time (derived) 20 AUG 2020 16:59

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

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)	15:58 (24 HR)
Collection date and time (derived)	20 AUG 2020 15:58

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

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	16:13	20 AUG 2020 16:13
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

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 16:28:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 17:34

PC Open Date & Time

20 AUG 2020 17:19

PC Close Date & Time

20 AUG 2020 19:49

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.8 °F

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

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

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 20 AUG 2020 20:45

PC Open Date & Time 20 AUG 2020 20:44

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 16:28:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☒

No ☐

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

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

21 AUG 2020 14:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °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

22 AUG 2020 13:40

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	99.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To TREAT pain or fever that has already occurred	True
To PREVENT pain or fever from occurring	False

PC Time Stamp	23 AUG 2020 17:45
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 AUG 2020 17:28

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 12:00

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 13:00

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

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

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

Please select one response below

None ☐

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 17:34

PC Open Date & Time

20 AUG 2020 17:19

PC Close Date & Time

20 AUG 2020 19:49

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 20:46

PC Open Date & Time

20 AUG 2020 20:44

PC Close Date & Time

21 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 14:20

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 13:41

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 17:45

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 17:27

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 14:04

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 13:01

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 17:35
PC Open Date & Time	20 AUG 2020 17:19
PC Close Date & Time	20 AUG 2020 19:49

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

Repeated use of over-the-counter
pain reliever > 24 hours or some

interference with activity ☐

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 20:48
PC Open Date & Time	20 AUG 2020 20:44
PC Close Date & Time	21 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 14:22
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 13:41
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 17:47
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 17:29
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 14:04
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 13:01
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3292259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 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

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	09:27 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:27
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)	71 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	12:07 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 12:07
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)	65 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	117 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	17 SEP 2020
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	17 SEP 2020
Collection time	09:23
Collection date and time (derived)	17 SEP 2020 09:23

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 17 SEP 2020

What was the treatment time? (00:00-23:59) 11:37 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 11:37

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

US3292259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 SEP 2020
Collection time (00:00-23:59)	09:44 (24 HR)
Collection date and time (derived)	17 SEP 2020 09:44

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)			17 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:10	17 SEP 2020 10:10
Nasopharyngeal Swab 2	No		

US3292259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 12:10

PC Open Date & Time

17 SEP 2020 11:57

PC Close Date & Time

17 SEP 2020 14:27

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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	18 SEP 2020 03:40
PC Open Date & Time	17 SEP 2020 15:22
PC Close Date & Time	18 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 12:03

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

19 SEP 2020 12:46

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

21 SEP 2020 06:50

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 SEP 2020 12:02

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 6

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

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

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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

96.2 °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

22 SEP 2020 12:01

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

95.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 15:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 12:11

PC Open Date & Time

17 SEP 2020 11:57

PC Close Date & Time

17 SEP 2020 14:27

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 03:41

PC Open Date & Time

17 SEP 2020 15:22

PC Close Date & Time

18 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 12:04

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 12:47

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 06:50

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 12:02

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 12:02

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 SEP 2020 15:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 12:11
PC Open Date & Time	17 SEP 2020 11:57
PC Close Date & Time	17 SEP 2020 14:27

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

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

No ☒

Yes ☐

PC Time stamp	18 SEP 2020 03:41
PC Open Date & Time	17 SEP 2020 15:22
PC Close Date & Time	18 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 12:04
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 12:47
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 06:50
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 12:02
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 12:03
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 15:17
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3292259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 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

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	12:03 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 12:03
Temperature (xxx.x)	36.6 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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	81 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3292259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 OCT 2020
Collection time (00:00-23:59)	12:13 (24 HR)
Collection date and time (derived)	15 OCT 2020 12:13

US3292259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:30:46

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	20 OCT 2020 00:55:58
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 03:11:59

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 10:10:09

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	True
Cough	True
Shortness of breath	False
Difficulty breathing	False
Fatigue	True
Muscle aches	True
Body aches	True
Headache	True
New loss of taste	False
New loss of smell	False
Sore throat	True
Congestion	True
Runny nose	True
Nausea	True
Vomiting	False
Diarrhea	True
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	19 NOV 2020 12:01:55
Patient Cloud Open Date & Time	17 NOV 2020 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
127 of 4261	

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

21 NOV 2020 23:59

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	24 NOV 2020 08:52:03
Patient Cloud Open Date & Time	24 NOV 2020 00:01
Patient Cloud Close Date & Time	28 NOV 2020 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 NOV 2020 00:21:30
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

28 NOV 2020 19:35:28

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 DEC 2020 00:51:34
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	12 DEC 2020 03:25:58
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 DEC 2020 11:55:40
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:01:40

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	02 JAN 2021 04:01:11
Patient Cloud Open Date & Time	02 JAN 2021 00:01
Patient Cloud Close Date & Time	06 JAN 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	09 JAN 2021 05:26:28
Patient Cloud Open Date & Time	09 JAN 2021 00:01
Patient Cloud Close Date & Time	13 JAN 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	16 JAN 2021 00:52:44
Patient Cloud Open Date & Time	16 JAN 2021 00:01
Patient Cloud Close Date & Time	20 JAN 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 JAN 2021 07:22:43
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 06:37:32

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 FEB 2021 06:52:54

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	13 FEB 2021 00:02:19
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	20 FEB 2021 01:12:00
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 FEB 2021 00:01:52
Patient Cloud Open Date & Time	27 FEB 2021 00:01
Patient Cloud Close Date & Time	03 MAR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	06 MAR 2021 00:01:36
Patient Cloud Open Date & Time	06 MAR 2021 00:01
Patient Cloud Close Date & Time	10 MAR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

13 MAR 2021 04:32:38

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 00:58:59

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 MAR 2021 00:01:49
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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	03 APR 2021 07:11:25
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 APR 2021 03:01:39
Patient Cloud Open Date & Time	10 APR 2021 00:01
Patient Cloud Close Date & Time	14 APR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

17 APR 2021 00:02:07

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 00:24:09

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAY 2021 00:09:31

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 264
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

12 MAY 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 271
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 278
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 299

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

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

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

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

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

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

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 ☐

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

14 JUL 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 355
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	07 AUG 2021 00:01
Patient Cloud Close Date & Time	11 AUG 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 369

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

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

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

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

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

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

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 ☐

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 397
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 411
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

02 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 418
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 OCT 2021 00:01
Patient Cloud Close Date & Time	20 OCT 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 432
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 460
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

18 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

22 DEC 2021 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 516
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 JAN 2022 00:01
Patient Cloud Close Date & Time	19 JAN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 523

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

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

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

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

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

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

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 ☐

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 JAN 2022 00:01
Patient Cloud Close Date & Time	26 JAN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	29 JAN 2022 00:01
Patient Cloud Close Date & Time	02 FEB 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 544
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 FEB 2022 00:01
Patient Cloud Close Date & Time	16 FEB 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 558

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 MAR 2022 00:01
Patient Cloud Close Date & Time	16 MAR 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 586

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

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

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

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

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

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

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 ☐

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

26 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 593

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

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

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

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

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

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

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 ☐

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 600
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2022 00:01
Patient Cloud Close Date & Time	15 JUN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2022 00:01
Patient Cloud Close Date & Time	06 JUL 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	09 JUL 2022 00:01
Patient Cloud Close Date & Time	13 JUL 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2022 00:01
Patient Cloud Close Date & Time	27 JUL 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 712
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 719

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

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

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 726

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

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

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Patient Cloud Open Date & Time	13 AUG 2022 00:01
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Patient Cloud Close Date & Time	17 AUG 2022 23:59
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US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 754

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

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

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

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

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

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

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 ☐

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT	DAY 768
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <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"/>

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 775

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

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

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

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

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

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

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 ☐

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 782

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

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

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

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

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

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

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 ☐

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

12 OCT 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Date and time of submission	
Patient Cloud Open Date & Time	15 OCT 2022 00:01
Patient Cloud Close Date & Time	19 OCT 2022 23:59

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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

Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2022 00:01
Patient Cloud Close Date & Time	26 OCT 2022 23:59

US3292259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:28:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 23:13:29

US3292259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 16 FEB 2021

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

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 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	VISIT4

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 APR 2021
Time of assessment (00:00-23:59)	13:14 (24 HR)
Vital Signs Date and Time (derived)	7 APR 2021 13:14
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 APR 2021

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

US3292259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 APR 2021
Collection time (00:00-23:59)	13:34 (24 HR)
Collection date and time (derived)	7 APR 2021 13:34

US3292259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:49:28

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Data signed: (b) (4) 22 Feb 2021 21:29:50

Generated On: 09 Jun 2021 16:28:39

Date of Contact	13 NOV 2020
Time of Contact	13:23
Date and Time of Contact (derived)	13 NOV 2020 13:23
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

Date	08 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:49:27

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Symptom Day

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

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Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:49:27

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

Date	09 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (3)

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Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	10 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	11 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:49:27

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Symptom Day

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

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	12 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (6)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

Date	13 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (7)

Data signed: (b) (4) 22 Apr 2021 15:49:27

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

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Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	14 NOV 2020	
Assessment Not Done	False	
O2 Saturation	ND - Not Done	
O2 Saturation Units	%	
Temperature	ND - Not Done	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input checked="" type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input checked="" type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Form: Symptom Log (8)

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Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (8)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

Date	15 NOV 2020
------	-------------

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

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

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

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

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

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

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

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

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (9)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (10)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Form: Symptom Log (10)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

Date	16 NOV 2020
------	-------------

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

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

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

Temperature	37.3 C
-------------	--------

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

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

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

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

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Form: Symptom Log (10)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (10)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

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Form: Symptom Log (11)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Form: Symptom Log (11)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

Date	17 NOV 2020
------	-------------

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

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

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

Temperature	36.0 C
-------------	--------

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

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

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

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

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Form: Symptom Log (11)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Form: Symptom Log (11)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Form: Symptom Log (12)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	18 NOV 2020	
Assessment Not Done	False	
O2 Saturation	100 %	
O2 Saturation Units	%	
Temperature	36.0 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

Date	19 NOV 2020
------	-------------

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

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

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

Temperature	36.2 C
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☐
Moderate ☒
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Feb 2021 21:29:50

Generated On: 09 Jun 2021 16:28:39

Date of Visit 16 NOV 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 16 NOV 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 22 Feb 2021 21:29:50

Generated On: 09 Jun 2021 16:28:39

[Generate Next COVID-19 Assessment](#)

Yes ☒

No ☐

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Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 22 Feb 2021 21:29:50

Generated On: 09 Jun 2021 16:28:39

Date of Contact	21 DEC 2020
Time of Contact	09:58
Date and Time of Contact (derived)	21 DEC 2020 09:58
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

Date	19 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

Date	20 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

Date	22 DEC 2020
------	-------------

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

O2 Saturation	98 %
---------------	------

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

Temperature	36.9 C
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

Date	23 DEC 2020
------	-------------

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

O2 Saturation	97 %
---------------	------

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

Temperature	36.5 C
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

Date	24 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

Date	25 DEC 2020
------	-------------

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

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

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

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

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

Date	26 DEC 2020
------	-------------

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

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

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

Temperature	36.5 C
-------------	--------

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

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

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

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

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EAB) (1725)

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Symptom Day

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

Date	27 DEC 2020
------	-------------

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

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

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

Temperature	36.5 C
-------------	--------

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

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

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

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

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

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

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 22 Feb 2021 21:29:51

Generated On: 09 Jun 2021 16:28:39

Nasal Congestion

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 22 Feb 2021 21:29:50

Generated On: 09 Jun 2021 16:28:39

Date of Visit 22 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒ No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐ No ☒

Date of Test 22 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒ Nasal Swab ☐ Saliva Test ☐ Other ☐

Other, specify

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐ No ☒

If yes, provide lab information below

Lab/ Institution Test Performed

CLIA Certified? Yes ☐ No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	18 NOV 2020
Day 5	Yes	20 NOV 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	24 DEC 2020
Day 5	Yes	26 DEC 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	16 NOV 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	16 NOV 2020
Time of assessment (00:00-23:59)	17:22 (24 HR)
Vital Signs Date and Time (derived)	16 NOV 2020 17:22
Height (xxx.x)	162.6 cm
Weight (xxx.x)	77.1 kg
Temperature (xxx.x)	37.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	129 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

16 NOV 2020

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

US3292259

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

16 NOV 2020

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	22 DEC 2020
Time of assessment (00:00-23:59)	12:30 (24 HR)
Vital Signs Date and Time (derived)	22 DEC 2020 12:30
Height (xxx.x)	160.02 cm
Weight (xxx.x)	77.11 kg
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	81 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 DEC 2020

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

US3292259

Folder: Illness Visit Day 1 (1)

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

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

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

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

22 DEC 2020

US3292259

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 JAN 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3292259

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Date of updated informed consent (dd MMM yyyy)	28 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 (dd MMM yyyy)	28 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

US3292259

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

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

US3292259

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	09:21 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 09:21
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3292259

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Height	ND - Not Done
Weight	ND - Not Done
BMI (xxx.x)	
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	28 JAN 2021
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	28 JAN 2021 10:40
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)	85 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)	89 mmHg
Diastolic Blood Pressure units	MMHG

US3292259

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 JAN 2021

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

US3292259

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

Form: Pregnancy Test

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	28 JAN 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3292259

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

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

What was the treatment date? (dd MMM yyyy) 28 JAN 2021

What was the treatment time? (00:00-23:59) 10:10 (24 HR)

Treatment Date and Time (derived) 28 JAN 2021 10:10

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

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00-23:59)	09:28 (24 HR)
Collection date and time (derived)	28 JAN 2021 09:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	28 JAN 2021
Collection time (00:00 - 23:59)	09:40
Collection Date and Time (derived)	28 JAN 2021 09:40

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:52

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

4 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:29:53

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Continuing Flag	1
OLD29 Placebo Flag	1

US3292259

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD29

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	11 MAR 2021
Time of assessment (00:00-23:59)	09:15 (24 HR)
Vital Signs Date and Time (derived)	11 MAR 2021 09:15
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Date of assessment (dd MMM yyyy)	
Time of assessment (00:00-23:59)	
Vital Signs Date and Time (derived)	
Temperature (xxx.x)	
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	
Pulse units	
Respiratory Rate (xxx)	
Respiratory Rate units	
Systolic Blood Pressure (xxx)	
Systolic Blood Pressure units	
Diastolic Blood Pressure (xxx)	
Diastolic Blood Pressure units	

US3292259

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

11 MAR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was the pregnancy test performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of test (<i>dd MMM yyyy</i>)	11 MAR 2021
Test performed	Urine <input checked="" type="radio"/>
	Serum <input type="radio"/>
Result	Positive <input type="radio"/>
	Negative <input checked="" type="radio"/>
Was FSH sample collected?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
Collection date	
Collection time	
Collection date and time (derived)	

US3292259

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:21:50

Generated On: 09 Jun 2021 16:28:39

Was study treatment given? Yes ☐
No ☒

If No, reason not given

Participant declined due to Adverse Event ☒
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

What was the study treatment? (Unblinded)

What was the treatment date? (dd MMM yyyy)

What was the treatment time? (00:00-23:59)

Treatment Date and Time (derived)

Which arm was used to give treatment? Left Arm ☐
Right Arm ☐

What was the frequency of the study treatment dosing?

What was the route of administration for the study treatment?

US3292259

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:50

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292259

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	7 APR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	7 APR 2021
Time of assessment (00:00-23:59)	13:14 (24 HR)
Vital Signs Date and Time (derived)	7 APR 2021 13:14
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)	89 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	141 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292259

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

7 APR 2021

Any abnormal and clinically significant findings should be recorded on the Adverse Event or Medical History eCRF, as applicable.

US3292259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:21:51

Generated On: 09 Jun 2021 16:28:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	7 APR 2021
Collection time (00:00-23:59)	13:34 (24 HR)
Collection date and time (derived)	7 APR 2021 13:34

US3292259

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 22 Feb 2021 21:29:50

Generated On: 09 Jun 2021 16:28:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	LEFT EYE INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	30 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	17 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	BODY ACHES
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)	7 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)	24 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	MUSCLE ACHES
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)	7 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)	16 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____ _____	
Narrative _____ _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____ _____	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	CHILLS
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)	7 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)	17 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	FATIGUE
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)	7 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)	21 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	7 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)	18 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	HEADACHES
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)	7 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)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	FEVER
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 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)	17 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	COUGH
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 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)	22 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	SHORTNESS OF BREATH
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 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)	17 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	DIFFICULTY BREATHING
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 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)	17 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	SORE THROAT
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 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)	21 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (13)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	NASAL CONGESTION
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 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)	17 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (14)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
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)	16 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)	19 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (15)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	RUNNY NOSE
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)	18 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)	21 NOV 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (16)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	USA-US072-2021-MRNA-1273-P30 1000006
Adverse event	ABDOMINAL HERNIA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 DEC 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)	29 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	31 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	04 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (17)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/>
	Related <input type="radio"/>
	Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/>
	Dose Delayed <input type="radio"/>
	Investigational Product <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 (17)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

PT WAS CONTACTED VIA
PHONE TO CONDUCT D149 SC,
DURING CALL, PT REPORTED
TO HAVE BEEN HOSPITALIZED
DUE TO ABDOMINAL HERNIA.

PT WAS ADMITTED ON
29DEC2020. PT WAS
HOSPITALIZED FOR 8 DAYS
DUE TO SURGERY TO FIX
ABDOMINAL HERNIA. WAS
DISCHARGED ON 06JAN2021.
WILL REQUEST RECORDS.

Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 DEC 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)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (18)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	MUSCLE ACHES
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 DEC 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)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (19)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	NAUSEA
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	22 DEC 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)	23 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (20)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (21)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	DIFFICULTY BREATHING
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)	25 DEC 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)	26 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (21)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

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Folder: Adverse Events

Form: Adverse Events (22)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	NASAL CONGESTION
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)	26 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	

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Folder: Adverse Events

Form: Adverse Events (22)

Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	RUNNY NOSE
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)	26 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	

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Folder: Adverse Events

Form: Adverse Events (23)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative	
<hr/>	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

US3292259

Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	USA-US072-2021-MRNA-1273-P30 1000006
Adverse event	ABDOMINAL HERNIA REPAIR INFECTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	02 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 FEB 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input 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)	13 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	18 FEB 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
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Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 03 May 2021 14:18:44

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Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	

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Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

PHONE CALL TO SUBJECT TO ASSESS DAY 179 SC, SUBJECT INFORMED SITE THAT SHE IS CURRENTLY IN THE HOSPITAL.

SUBJECT WAS ADMITTED TO METHODIST METROPOLITAN ON 2/12/21 FOR DRAINING FROM WHERE HER ABDOMINAL HERNIA WAS REPAIRED. SHE WAS TOLD THAT IT IS A SEVERE INFECTION AND THAT IT WOULD NEED TO BE DRAINED.

IV ANTIBIOTICS WERE STARTED ON 2/12/21 BUT SUBJECT STATES THAT HER IV WAS NOT PLACED CORRECTLY AND SHE WAS NOT RECEIVING ANY OF THE MEDICATION. A NEW IV WAS STARTED AND SHE IS NOW RECEIVING MEDICATION. A PROCEDURE TO DRAIN THE PUSS THAT WAS DRAINING FROM HER ABDOMINAL HERNIA WAS DONE ON 2/15/21 WITH THE POSSIBILITY OF ANOTHER ROUND OF DRAINING PENDING THE OUTCOME OF THE FIRST PROCEDURE. SHE DOES NOT KNOW THE NAME OF MEDICATIONS SHE IS BEING GIVEN, SITE DID ADVISE HER THAT WE WOULD REQUEST

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Folder: Adverse Events

Form: Adverse Events (24)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

RECORDS AND SHE AGREED.
SHE WAS ADVISED TO CALL US
WITH ANY CHANGES OR
CONCERNS. SUBJECT WAS
ALSO TESTED FOR COVID 19
ON 2/12/21 WITH A NEGATIVE
RESULT. CONMED LOG WILL
BE UPDATED WHEN WE
RECEIVE MEDICAL RECORDS .

SUBJECT HAD REPORTED
BEING ADMITTED TO THE
HOSPITAL ON 12FEB.
HOWEVER, MEDICAL RECORDS
STATE THAT ADMISSION DATE
WAS 13FEB2021

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 (25)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	PAIN AT INJECTION SITE
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)	28 JAN 2021
Start time (00:00-23:59)	16:00 (24 HR)
AE start date and time (derived)	28 JAN 2021 16:00
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Data signed: (b) (4) 03 May 2021 14:18:44

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Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input type="radio"/> Related <input checked="" type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only)	

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Folder: Adverse Events

Form: Adverse Events (26)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	BROKEN BOTTOM INCISOR
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 DEC 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)	20 MAR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (26)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae: _____	
Narrative _____	
Serious Adverse Event Derived (CSA Programming Field Only)	0
Medically Attended AE Derived (CSA Programming Field Only)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (27)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

AEID	
Adverse event	ABDOMINAL PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	29 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 type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (27)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
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)	

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 21:29:50

Generated On: 09 Jun 2021 16:28:39

Were any prior/concomitant medications and/or vaccinations taken?

Yes ☒

No ☐

If Yes, please complete Prior/Concomitant Medication and Vaccination form.

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication TOPIRAMATE

Prophylaxis Yes ☐
No ☒

Indication HEADACHE

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication HYDROCODONE/APAP

Prophylaxis Yes ☐
No ☒

Indication LOW BACK PAIN

Dose per administration 10-325

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 1998	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication JANUVIA

Prophylaxis Yes ☐
No ☒

Indication DIABETES TYPE II

Dose per administration 50

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN NOV 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication MILD FEVER

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 (4)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication PREDNISOLONE EYE DROPS 1 %

Prophylaxis Yes ☐
No ☒

Indication EYE INFECTION

Dose per administration 1

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify DROP

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) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	OPHTHALMIC	
Start date (dd MMM yyyy)	01 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	17 SEP 2020	
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 (6)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication BACLOFEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SORENESS

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		7 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 NOV 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☐
No ☒

Indication SHINGLES

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 (7)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	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)		6 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) 6 DEC 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 (8)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HYPERCHOLESTEROLEMIA

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 AUG 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 (9)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication BACLOFEN

Prophylaxis Yes ☐
No ☒

Indication MUSCLE ACHES

Dose per administration 10

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☒
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 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 (10)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication SHINGLES VACCINE

Prophylaxis Yes ☒
No ☐

Indication 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 (10)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	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)		06 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		06 DEC 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 (11)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN AT INJECTION SITE

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 (11)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	28 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication CEFEPIME HCL

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 2

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

Q12HR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 100

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

QHR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 1500

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

UT DICT

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 650

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication HYDROCODONE-ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 5/325

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication MAGNESIUM SULFATE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 100

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

UT DICT

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication MORPHINE SULFATE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 2

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 800

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

UT DICT

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication POTASSIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 100

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

UT DICT

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 1000

Dose unit mg ☐
ug ☐
mL ☒
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

Q10HR

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		16 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 800

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

UT DICT

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	FEEDING TUBE	
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="radio"/>	No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input type="radio"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 May 2021 14:18:46

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Name of Medication ONDANSETRON HCL

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 4

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

UT DICT

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication CEFTRIAXONE

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 1

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

UT DICT

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		13 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication GLUCAGON

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 1

Dose unit mg ☒
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☐

If dose unit is Other, specify

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☐
once ☐
unknown ☐
other ☒

If frequency is Other, specify

UT DICT

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

Dose per administration 2

Dose unit mg ☐
ug ☐
mL ☐
g ☐
IU ☐
tablet ☐
capsule ☐
puff ☐
Other ☒

If dose unit is Other, specify SLIDING SCALE

Frequency once daily ☐
twice daily ☐
three times daily ☐
four times daily ☐
every other day ☐
every week ☐
every month ☐
as needed ☒
once ☐
unknown ☐
other ☐

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☒
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	13 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	18 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication FLAGYL

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

Name of Medication CIPROFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication ABDOMINAL HERNIA REPAIR
INFECTION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 03 May 2021 14:18:46

Generated On: 09 Jun 2021 16:28:39

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	17 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	26 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Apr 2021 15:49:27

Generated On: 09 Jun 2021 16:28:39

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
29 DEC 2020	VENTRAL HERNIA REPAIR	Adverse Event	
29 DEC 2020	EXPLORATORY LAPAROTOMY	Adverse Event	
20 MAR 2021	BROKEN INCISOR REPAIR	Adverse Event	
13 FEB 2021	CAT SCAN - ABDOMEN/PELVIS	Adverse Event	
15 FEB 2021	ULTRASOUND GUIDED NEEDLE ASPIRATION	Adverse Event	
29 DEC 2020	OMENTECTOMY	Adverse Event	
29 DEC 2020	REMOVAL OF FB	Adverse Event	
29 DEC 2020	BILAT MYOCUT FLAPS	Adverse Event	

US3292259

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:28:39

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent
by participant, Protocol deviation, or Other, specify

US3292259

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:28:39

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

If reason is AE, SAE, Physician Decision, Withdrawal of consent by
participant, Protocol deviation, or Other, specify

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	19/JAN/2021 13:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	18/FEB/2021 14:27
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

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	25/FEB/2021 15:57
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

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	01/APR/2021 09:53
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/APR/2021 09:51
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

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/APR/2021 14:49
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

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	30/APR/2021 15:02
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

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (8)

Data signed: (b) (4) 03 May 2021 14:18:47

Generated On: 09 Jun 2021 16:28:39

SAEID	USA-US072-2021-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	DOUGLAS
Investigator's Last Name	DENHAM
Site Address: Street	7940 FLOYD CURL DRIVE
Site Address: City	SAN ANTONIO
Site Address: State	
Site Address: Postal Code	78229
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	8
Date of submission (Pre-filled from custom function)	03/MAY/2021 09:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292259 (Prod: Clinical Trials of Texas, Inc)

US3292259

Form: Participant Creation

Generated On: 09 Jun 2021 16:28:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:20:06
User entered 'US3292259'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:56

US3292259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:39:42

US3292259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:57

US3292259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 12:39:42

US3292259

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'SCRN'	System	24 Aug 2020 12:39:42

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered (b) (6) 1970'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:58

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '50'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'YEARS'	System	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '50'	System	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Female (F)'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'l'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:39:56

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

[Month and Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Aug 2020'	System	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

[Year of Informed Consent \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2020'	System	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Amendment 2 (2)'	(b) (4), (b) (6)	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

[Was participant enrolled in the study?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

[If No, indicate reason for screen fail](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	20 Aug 2020 22:04:47

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 20:04:57

US3292259

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'l'	System	20 Aug 2020 22:04:55

US3292259

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:28:39

[Did the participant meet all eligibility criteria?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 22:04:55

US3292259

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:28:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:42:14

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 12:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:49:35
Data point term sent to Coder	System	24 Aug 2020 12:48:17
User entered 'low back surgery'	(b) (4), (b) (6)	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 1998'	(b) (4), (b) (6)	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 1998'	(b) (4), (b) (6)	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 1998'	System	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '1998'	System	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 1998'	System	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '1998'	System	24 Aug 2020 12:47:17

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal operation, LLT: Back surgery - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 12:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:49:35
Data point term sent to Coder	System	24 Aug 2020 12:48:17
User entered 'low back surgery'	(b) (4), (b) (6)	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 1999'	(b) (4), (b) (6)	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 1999'	(b) (4), (b) (6)	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 1999'	System	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '1999'	System	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 1999'	System	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '1999'	System	24 Aug 2020 12:47:30

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Abdominal hernia repair, LLT: Ventral hernia repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 12:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:49:35
Data point term sent to Coder	System	24 Aug 2020 12:48:17
User entered 'ventral hernia repair'	(b) (4), (b) (6)	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 2011'	(b) (4), (b) (6)	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 2011'	(b) (4), (b) (6)	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 2011'	System	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2011'	System	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 2011'	System	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2011'	System	24 Aug 2020 12:47:58

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Abdominal hernia repair, LLT: Ventral hernia repair - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 12:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:49:35
Data point term sent to Coder	System	24 Aug 2020 12:49:18
User entered 'ventral hernia repair'	(b) (4), (b) (6)	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 2017'	(b) (4), (b) (6)	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 2017'	(b) (4), (b) (6)	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 2017'	System	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2017'	System	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 2017'	System	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2017'	System	24 Aug 2020 12:48:20

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of MH# 3 and #4 VENTRAL HERNIA REPAIR was performed in UN UNK 2011 and 2017. Please review and update if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 16:14:10
Query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of MH# 3 and #4 VENTRAL HERNIA REPAIR was performed in UN UNK 2011 and 2017. Please review and update if appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	22 Sep 2020 15:31:02
User opened query 'Per DM CLR: Please review if this Condition is still ongoing as it was noted that a surgical procedure of MH# 3 and #4 VENTRAL HERNIA REPAIR was performed in UN UNK 2011 and 2017. Please review and update if appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 13:43:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Ventral hernia - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 12:49:35
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 12:49:35
Data point term sent to Coder	System	24 Aug 2020 12:49:18
User entered 'ventral hernia'	(b) (4), (b) (6)	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 2009'	(b) (4), (b) (6)	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Sep 2020 15:30:53
User entered 'Yes (Y)'	Dawn Killian (b) (4)	24 Aug 2020 12:48:42
	(b) (4), (b) (6)	

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

If No, please specify the stop date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'UN UNK 2017' reason for change:	(b) (4)	
Data Entry Error	Dawn Killian (b) (4)	22 Sep 2020 15:30:53
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 2009'	System	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2009'	System	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 2017'	System	22 Sep 2020 15:30:53
User entered empty.	System	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2017'	System	22 Sep 2020 15:30:53
User entered empty.	System	24 Aug 2020 12:48:42

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 12:49:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	24 Aug 2020 12:49:36
Data point term sent to Coder	System	24 Aug 2020 12:49:18
User entered 'diabetes type II'	(b) (4), (b) (6)	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un Nov 2019'	(b) (4), (b) (6)	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Nov 2019'	System	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2019'	System	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	24 Aug 2020 12:49:13

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Low back pain - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	24 Aug 2020 12:50:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 12:50:33
Data point term sent to Coder	System	24 Aug 2020 12:50:21
User entered 'low back pain'	(b) (4), (b) (6)	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'un UNK 1998'	(b) (4), (b) (6)	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Jan 1998'	System	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '1998'	System	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	24 Aug 2020 12:49:22

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Skin injuries NEC, PT: Contusion, LLT: Bruise of head - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 16:11:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Aug 2020 16:11:39
Data point term sent to Coder	System	24 Aug 2020 12:51:23
User entered 'head contusion'	(b) (4), (b) (6)	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '15 May 2020'	(b) (4), (b) (6)	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '15 May 2020'	(b) (4), (b) (6)	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'May 2020'	System	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2020'	System	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'May 2020'	System	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2020'	System	24 Aug 2020 12:50:46

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User coded data point as SOC: Nervous system disorders, HLT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 10:33:45
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	31 Aug 2020 10:33:45
Data point term sent to Coder	System	25 Aug 2020 16:34:58
User entered 'Headaches secondary to head contusion'	Dawn Killian (b) (4)	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '15 May 2020'	(b) (4) Dawn Killian (b) (4)	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Dawn Killian (b) (4)	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Dawn Killian (b) (4)	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Dawn Killian (b) (4)	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'May 2020'	System	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2020'	System	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	25 Aug 2020 16:34:18

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Elevated cholesterol, PT: Hypercholesterolaemia, LLT: Hypercholesterolemia - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	20 Apr 2021 15:00:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Apr 2021 15:00:37
Data point term sent to Coder	System	20 Apr 2021 14:59:50
User entered 'Hypercholesterolemia'	(b) (4), (b) (6)	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '15 Aug 2020'	(b) (4), (b) (6)	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4), (b) (6)	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4), (b) (6)	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'Aug 2020'	System	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '2020'	System	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:39

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	20 Apr 2021 14:58:57

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '14:40'	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '20 Aug 2020 14:40'	System	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '160.0' cm	(b) (4) (b) (4), (b) (6)	24 Aug 2020 12:53:14
DataPoint set to visible.	System	20 Aug 2020 22:04:55

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '86.2' kg	(b) (4), (b) (6)	24 Aug 2020 12:53:14
DataPoint set to visible.	System	20 Aug 2020 22:04:55

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
Amendment Manager: User entered '33.67188'	System	17 Sep 2020 00:17:05
User entered '33.7'	System	24 Aug 2020 12:53:14
DataPoint set to visible.	System	20 Aug 2020 22:04:55

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'kg/m2'	System	24 Aug 2020 12:53:14
DataPoint set to visible.	System	20 Aug 2020 22:04:55

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 12:14:20
Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	22 Dec 2020 16:42:52
User entered empty; reason for change Data Entry Error	(b) (4)	22 Dec 2020 16:42:47
User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 17:07:02
User entered 'Other (Other)'	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg from each field.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 21:30:10
Query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg from each field.' answered with 'Unable to remove units. Fields are not editable.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 17:30:46
User opened query 'Per CDM: Pulse, Respiratory Rate, Systolic/Diastolic Blood Pressure is recorded as Not Done. Kindly remove beats/min, breaths/min, or mmHg from each field.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 14:12:42
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'bpm'	System	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'breaths/min'	System	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'mmHg'	System	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'mmHg'	System	24 Aug 2020 12:53:14

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50

US3292259

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50

US3292259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:53:24

US3292259

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:53:24

US3292259

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:54:19

US3292259

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:39

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:54:19

US3292259

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:39

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:54:19

US3292259

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:39

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:54:19

US3292259

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:39

If Surgically sterile, date of surgery (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:54:19

US3292259

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:39

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:54:19

US3292259

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:39

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:54:19

US3292259

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:39

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:54:19

US3292259

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:54:33

US3292259

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:54:33

US3292259

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Urine (URINE)'	(b) (4), (b) (6)	24 Aug 2020 12:54:33

US3292259

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	24 Aug 2020 12:54:33

US3292259

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:54:33

US3292259

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:54:33

US3292259

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:54:33

US3292259

Folder: Screening

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	24 Aug 2020 12:54:33

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Personal Care and in-home services](#) (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'l'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:55:18

US3292259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:55:39

US3292259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:55:39

US3292259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	24 Aug 2020 12:55:39

US3292259

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'VISIT1'	System	24 Aug 2020 12:55:39

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '20 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:54:22

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 06:02:12
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 06:02:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 21:54:22
User entered '144351' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:54:22

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 21:54:22

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:56:21

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:56:21

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:56:21

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:56:21

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:56:21

US3292259

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:39

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:37:31
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:51:29

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User accepted default value 'Pre-Dose (PREDOSE)'		24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '15:52'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '20 Aug 2020 15:52'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '036.6' C	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '071'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'bpm'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '15'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'breaths/min'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '110'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '075'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered missing code ND - Not Done.	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User accepted default value 'Post-Dose (POSTDOSE)'		24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17:30'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '20 Aug 2020 17:30'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '36.6' C	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '68'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'bpm'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '16'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'breaths/min'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '115'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '79'	(b) (4), (b) (6)	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	24 Aug 2020 12:58:03

US3292259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:58:14

US3292259

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:14

US3292259

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:58:19

US3292259

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:19

US3292259

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:19

US3292259

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:19

US3292259

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:19

US3292259

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:19

US3292259

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:19

US3292259

Folder: Visit 1 Day 1

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered empty.	System	24 Aug 2020 12:58:19

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '20 Aug 2020'	(b) (4), (b) (6)	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '16:59'	(b) (4), (b) (6)	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered '20 Aug 2020 16:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'ONCE'	System	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 22:05:22

US3292259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:58:40

US3292259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:58:40

US3292259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '15:58'	(b) (4), (b) (6)	24 Aug 2020 12:58:40

US3292259

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered '20 Aug 2020 15:58'	System	24 Aug 2020 12:58:40

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 Aug 2020'	(b) (4), (b) (6)	24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16:13'	(b) (4), (b) (6)	24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered '20 Aug 2020 16:13'	System	24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4), (b) (6)	24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered empty.	System	24 Aug 2020 12:58:56

US3292259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:59:03

US3292259

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'I'	System	24 Aug 2020 12:59:03

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:33:53', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3c9d13d5-2a37-43d8-9ca2-79abed2a61f8'	System	20 Aug 2020 22:34:18
User entered 'Yes (Y)'	System	20 Aug 2020 22:34:18

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:01', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3c9d13d5-2a37-43d8-9ca2-79abed2a61f8' User entered '97.8'	System	20 Aug 2020 22:34:18
	System	20 Aug 2020 22:34:18

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:08', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3c9d13d5-2a37-43d8-9ca2-79abed2a61f8'	System	20 Aug 2020 22:34:18
User entered 'No (N)'	System	20 Aug 2020 22:34:18

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:14', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3c9d13d5-2a37-43d8-9ca2-79abed2a61f8' User entered '20 Aug 2020 17:34'	System	20 Aug 2020 22:34:18
	System	20 Aug 2020 22:34:18

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 17:19'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 19:49'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:44:36', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2c5e773-7d3e-4fca-9cd8-3bd98e765fce' User entered 'Yes (Y)'	System	21 Aug 2020 01:45:37
	System	21 Aug 2020 01:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:45:00', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2c5e773-7d3e-4fca-9cd8-3bd98e765fce' User entered '97.8'	System	21 Aug 2020 01:45:37
	System	21 Aug 2020 01:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:45:14', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2c5e773-7d3e-4fca-9cd8-3bd98e765fce' User entered 'Yes (Y)'	System	21 Aug 2020 01:45:37
	System	21 Aug 2020 01:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Tylenol (500mg) for fever ' (Site from System).	(b) (4), (b) (6)	01 Sep 2020 19:24:56
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:45:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2c5e773-7d3e-4fca-9cd8-3bd98e765fce' User entered '1'	Kristy Trevino (b) (4) (b) (4)	29 Aug 2020 16:06:02
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	21 Aug 2020 01:45:37
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:45:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2c5e773-7d3e-4fca-9cd8-3bd98e765fce' User entered '1'	System	21 Aug 2020 01:45:37
User entered '1'	System	21 Aug 2020 01:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:45:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2c5e773-7d3e-4fca-9cd8-3bd98e765fce' User entered '0'	System	21 Aug 2020 01:45:37
	System	21 Aug 2020 01:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:45:34', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2c5e773-7d3e-4fca-9cd8-3bd98e765fce' User entered '20 Aug 2020 20:45'	System	21 Aug 2020 01:45:37
	System	21 Aug 2020 01:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 20:44'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 2'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:19:27', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ef29b842-6a00-4929-a0a2-624e2d169d2a' User entered 'Yes (Y)'	System	21 Aug 2020 19:20:05
	System	21 Aug 2020 19:20:05

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:19:33', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ef29b842-6a00-4929-a0a2-624e2d169d2a' User entered '99.1'	System	21 Aug 2020 19:20:05
	System	21 Aug 2020 19:20:05

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:19:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ef29b842-6a00-4929-a0a2-624e2d169d2a'	System	21 Aug 2020 19:20:05
User entered 'Yes (Y)'	System	21 Aug 2020 19:20:05

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Subject took Tylenol 500 mg for Fatigue' (Site from System).	(b) (4)	01 Sep 2020 19:25:22
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Kristy Trevino (b) (4)	29 Aug 2020 16:07:11
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:19:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ef29b842-6a00-4929-a0a2-624e2d169d2a'	(b) (4)	
User entered '1'	System	21 Aug 2020 19:20:05
	System	21 Aug 2020 19:20:05
	System	21 Aug 2020 19:20:05

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:19:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ef29b842-6a00-4929-a0a2-624e2d169d2a' User entered '0'	System	21 Aug 2020 19:20:05
	System	21 Aug 2020 19:20:05

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:20:02', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ef29b842-6a00-4929-a0a2-624e2d169d2a' User entered '21 Aug 2020 14:20'	System	21 Aug 2020 19:20:05
	System	21 Aug 2020 19:20:05

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 3'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:40:27', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '53ba8f27-fec7-498f-ae18-843f845d53db' User entered 'Yes (Y)'	System	22 Aug 2020 18:40:43
	System	22 Aug 2020 18:40:43

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:40:32', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '53ba8f27-fec7-498f-ae18-843f845d53db' User entered '97.2'	System	22 Aug 2020 18:40:43
	System	22 Aug 2020 18:40:43

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:40:35', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '53ba8f27-fec7-498f-ae18-843f845d53db'	System	22 Aug 2020 18:40:43
User entered 'No (N)'	System	22 Aug 2020 18:40:43

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:40:42', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '53ba8f27-fec7-498f-ae18-843f845d53db' User entered '22 Aug 2020 13:40'	System	22 Aug 2020 18:40:43
	System	22 Aug 2020 18:40:43

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 4'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:44:42', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3aba5c67-914f-4c98-8042-978dbb8e76e9'	System	23 Aug 2020 22:45:08
User entered 'Yes (Y)'	System	23 Aug 2020 22:45:08

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:44:50', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3aba5c67-914f-4c98-8042-978dbb8e76e9' User entered '99.4'	System	23 Aug 2020 22:45:08
	System	23 Aug 2020 22:45:08

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:44:54', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3aba5c67-914f-4c98-8042-978dbb8e76e9'	System	23 Aug 2020 22:45:08
User entered 'Yes (Y)'	System	23 Aug 2020 22:45:08

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'Tylenol was taken for fever ' (Site from System).	(b) (4)	01 Sep 2020 19:25:35
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.'	Kristy Trevino (b) (4)	29 Aug 2020 16:10:03
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:44:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3aba5c67-914f-4c98-8042-978dbb8e76e9'	(b) (4)	
User entered '1'	System	23 Aug 2020 22:45:08
	System	23 Aug 2020 22:45:08
	System	23 Aug 2020 22:45:08

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:44:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3aba5c67-914f-4c98-8042-978dbb8e76e9' User entered '0'	System	23 Aug 2020 22:45:08
	System	23 Aug 2020 22:45:08

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:45:07', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '3aba5c67-914f-4c98-8042-978dbb8e76e9' User entered '23 Aug 2020 17:45'	System	23 Aug 2020 22:45:08
	System	23 Aug 2020 22:45:08

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 5'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:27:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2da454ce-bea5-484e-b674-d71e10c1aef6' User entered 'Yes (Y)'	System	24 Aug 2020 22:28:54
	System	24 Aug 2020 22:28:54

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:28:40', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2da454ce-bea5-484e-b674-d71e10c1aef6' User entered '98.2'	System	24 Aug 2020 22:28:54
	System	24 Aug 2020 22:28:54

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:28:45', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2da454ce-bea5-484e-b674-d71e10c1aef6'	System	24 Aug 2020 22:28:54
User entered 'No (N)'	System	24 Aug 2020 22:28:54

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:28:51', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2da454ce-bea5-484e-b674-d71e10c1aef6' User entered '24 Aug 2020 17:28'	System	24 Aug 2020 22:28:54
	System	24 Aug 2020 22:28:54

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 6'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T12:00:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd4e0c4c-7025-4234-9aef-c97cd0d50beb' User entered 'Yes (Y)'	System	25 Aug 2020 17:00:59
	System	25 Aug 2020 17:00:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T12:00:35', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd4e0c4c-7025-4234-9aef-c97cd0d50beb' User entered '97.8'	System	25 Aug 2020 17:00:59
	System	25 Aug 2020 17:00:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T12:00:41', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd4e0c4c-7025-4234-9aef-c97cd0d50beb'	System	25 Aug 2020 17:00:59
User entered 'No (N)'	System	25 Aug 2020 17:00:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T12:00:52', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd4e0c4c-7025-4234-9aef-c97cd0d50beb' User entered '25 Aug 2020 12:00'	System	25 Aug 2020 17:00:59
	System	25 Aug 2020 17:00:59

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 7'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:00:35', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '4285adf7-b578-4152-811c-dd3c5763ec96' User entered 'Yes (Y)'	System	26 Aug 2020 18:01:19
	System	26 Aug 2020 18:01:19

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:00:40', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '4285adf7-b578-4152-811c-dd3c5763ec96' User entered '98.3'	System	26 Aug 2020 18:01:19
	System	26 Aug 2020 18:01:19

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:00:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '4285adf7-b578-4152-811c-dd3c5763ec96'	System	26 Aug 2020 18:01:19
User entered 'No (N)'	System	26 Aug 2020 18:01:19

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:00:47', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '4285adf7-b578-4152-811c-dd3c5763ec96' User entered '26 Aug 2020 13:00'	System	26 Aug 2020 18:01:19
	System	26 Aug 2020 18:01:19

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:33', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ea4470bc-5f77-43db-9832-cf9314682173'	System	20 Aug 2020 22:34:53
User entered 'Does not interfere with activity (2)'	System	20 Aug 2020 22:34:53

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:37', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ea4470bc-5f77-43db-9832-cf9314682173' User entered 'No (N)'	System	20 Aug 2020 22:34:53
	System	20 Aug 2020 22:34:53

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:41', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ea4470bc-5f77-43db-9832-cf9314682173' User entered 'No (N)'	System	20 Aug 2020 22:34:53
	System	20 Aug 2020 22:34:53

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:45', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ea4470bc-5f77-43db-9832-cf9314682173' User entered 'None (1)'	System	20 Aug 2020 22:34:53
	System	20 Aug 2020 22:34:53

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:49', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ea4470bc-5f77-43db-9832-cf9314682173' User entered '20 Aug 2020 17:34'	System	20 Aug 2020 22:34:53
	System	20 Aug 2020 22:34:53

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 17:19'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 19:49'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:46:11', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '01c2834d-4a87-4c45-b200-497649c96a3c'	System	21 Aug 2020 01:47:01
User entered 'None (1)'	System	21 Aug 2020 01:47:01

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:46:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '01c2834d-4a87-4c45-b200-497649c96a3c' User entered 'No (N)'	System	21 Aug 2020 01:47:01
	System	21 Aug 2020 01:47:01

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:46:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '01c2834d-4a87-4c45-b200-497649c96a3c' User entered 'No (N)'	System	21 Aug 2020 01:47:01
	System	21 Aug 2020 01:47:01

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:46:52', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '01c2834d-4a87-4c45-b200-497649c96a3c' User entered 'None (1)'	System	21 Aug 2020 01:47:01
	System	21 Aug 2020 01:47:01

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:46:58', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '01c2834d-4a87-4c45-b200-497649c96a3c' User entered '20 Aug 2020 20:46'	System	21 Aug 2020 01:47:01
	System	21 Aug 2020 01:47:01

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 20:44'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 2'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:20:14', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c3b3c043-1fba-4770-b159-a2a902f4659a' User entered 'None (1)'	System	21 Aug 2020 19:20:32
	System	21 Aug 2020 19:20:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:20:18', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c3b3c043-1fba-4770-b159-a2a902f4659a' User entered 'No (N)'	System	21 Aug 2020 19:20:32
	System	21 Aug 2020 19:20:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:20:21', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c3b3c043-1fba-4770-b159-a2a902f4659a' User entered 'No (N)'	System	21 Aug 2020 19:20:32
	System	21 Aug 2020 19:20:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:20:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c3b3c043-1fba-4770-b159-a2a902f4659a' User entered 'None (1)'	System	21 Aug 2020 19:20:32
	System	21 Aug 2020 19:20:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:20:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c3b3c043-1fba-4770-b159-a2a902f4659a' User entered '21 Aug 2020 14:20'	System	21 Aug 2020 19:20:32
	System	21 Aug 2020 19:20:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 3'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:40:47', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '956ad658-4125-487c-b591-0cd064ecc75b' User entered 'None (1)'	System	22 Aug 2020 18:41:05
	System	22 Aug 2020 18:41:05

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:40:52', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '956ad658-4125-487c-b591-0cd064ecc75b' User entered 'No (N)'	System	22 Aug 2020 18:41:05
	System	22 Aug 2020 18:41:05

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:40:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '956ad658-4125-487c-b591-0cd064ecc75b' User entered 'No (N)'	System	22 Aug 2020 18:41:05
	System	22 Aug 2020 18:41:05

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:40:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '956ad658-4125-487c-b591-0cd064ecc75b' User entered 'None (1)'	System	22 Aug 2020 18:41:05
	System	22 Aug 2020 18:41:05

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:02', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '956ad658-4125-487c-b591-0cd064ecc75b' User entered '22 Aug 2020 13:41'	System	22 Aug 2020 18:41:05
	System	22 Aug 2020 18:41:05

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 4'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:45:13', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'cc6d28cd-fcd8-44ce-86d0-bd6eb288c270'	System	23 Aug 2020 22:45:37
User entered 'None (1)'	System	23 Aug 2020 22:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:45:17', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'cc6d28cd-fcd8-44ce-86d0-bd6eb288c270'	System	23 Aug 2020 22:45:37
User entered 'No (N)'	System	23 Aug 2020 22:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:45:24', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'cc6d28cd-fcd8-44ce-86d0-bd6eb288c270'	System	23 Aug 2020 22:45:37
User entered 'No (N)'	System	23 Aug 2020 22:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:45:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'cc6d28cd-fcd8-44ce-86d0-bd6eb288c270' User entered 'None (1)'	System	23 Aug 2020 22:45:37
	System	23 Aug 2020 22:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:45:34', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'cc6d28cd-fcd8-44ce-86d0-bd6eb288c270' User entered '23 Aug 2020 17:45'	System	23 Aug 2020 22:45:37
	System	23 Aug 2020 22:45:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 5'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:26:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5941484a-62fe-431f-9d30-3bcfc2210941' User entered 'None (1)'	System	24 Aug 2020 22:27:14
	System	24 Aug 2020 22:27:14

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:26:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5941484a-62fe-431f-9d30-3bcfc2210941' User entered 'No (N)'	System	24 Aug 2020 22:27:14
	System	24 Aug 2020 22:27:14

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:27:02', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5941484a-62fe-431f-9d30-3bcfc2210941' User entered 'No (N)'	System	24 Aug 2020 22:27:14
	System	24 Aug 2020 22:27:14

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:27:07', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5941484a-62fe-431f-9d30-3bcfc2210941'	System	24 Aug 2020 22:27:14
User entered 'None (1)'	System	24 Aug 2020 22:27:14

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:27:09', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5941484a-62fe-431f-9d30-3bcfc2210941' User entered '24 Aug 2020 17:27'	System	24 Aug 2020 22:27:14
	System	24 Aug 2020 22:27:14

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 6'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T12:08:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '06c534dd-6ec2-4632-8306-a9218120693c'	System	25 Aug 2020 19:04:37
User entered 'None (1)'	System	25 Aug 2020 19:04:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:22', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '06c534dd-6ec2-4632-8306-a9218120693c' User entered 'No (N)'	System	25 Aug 2020 19:04:37
	System	25 Aug 2020 19:04:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '06c534dd-6ec2-4632-8306-a9218120693c' User entered 'No (N)'	System	25 Aug 2020 19:04:37
	System	25 Aug 2020 19:04:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '06c534dd-6ec2-4632-8306-a9218120693c' User entered 'None (1)'	System	25 Aug 2020 19:04:37
	System	25 Aug 2020 19:04:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:30', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '06c534dd-6ec2-4632-8306-a9218120693c' User entered '25 Aug 2020 14:04'	System	25 Aug 2020 19:04:37
	System	25 Aug 2020 19:04:37

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 7'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:00:52', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '39f393c0-5604-47e2-8f97-86bdd0eb1665'	System	26 Aug 2020 18:01:32
User entered 'None (1)'	System	26 Aug 2020 18:01:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:00:56', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '39f393c0-5604-47e2-8f97-86bdd0eb1665' User entered 'No (N)'	System	26 Aug 2020 18:01:32
	System	26 Aug 2020 18:01:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:00', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '39f393c0-5604-47e2-8f97-86bdd0eb1665' User entered 'No (N)'	System	26 Aug 2020 18:01:32
	System	26 Aug 2020 18:01:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:02', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '39f393c0-5604-47e2-8f97-86bdd0eb1665'	System	26 Aug 2020 18:01:32
User entered 'None (1)'	System	26 Aug 2020 18:01:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:04', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '39f393c0-5604-47e2-8f97-86bdd0eb1665' User entered '26 Aug 2020 13:01'	System	26 Aug 2020 18:01:32
	System	26 Aug 2020 18:01:32

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:34:56', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0fd3bd4a-a4c0-40a0-a07b-272a5cb031e5' User entered 'None (0)'	System	20 Aug 2020 22:35:41
	System	20 Aug 2020 22:35:41

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:35:00', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0fd3bd4a-a4c0-40a0-a07b-272a5cb031e5' User entered 'None (0)'	System	20 Aug 2020 22:35:41
	System	20 Aug 2020 22:35:41

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:35:15', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0fd3bd4a-a4c0-40a0-a07b-272a5cb031e5' User entered 'None (0)'	System	20 Aug 2020 22:35:41
	System	20 Aug 2020 22:35:41

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:35:22', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0fd3bd4a-a4c0-40a0-a07b-272a5cb031e5' User entered 'None (0)'	System	20 Aug 2020 22:35:41
	System	20 Aug 2020 22:35:41

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:35:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0fd3bd4a-a4c0-40a0-a07b-272a5cb031e5' User entered 'None (0)'	System	20 Aug 2020 22:35:41
	System	20 Aug 2020 22:35:41

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:35:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0fd3bd4a-a4c0-40a0-a07b-272a5cb031e5' User entered 'None (0)'	System	20 Aug 2020 22:35:41
	System	20 Aug 2020 22:35:41

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:35:31', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0fd3bd4a-a4c0-40a0-a07b-272a5cb031e5' User entered 'No (N)'	System	20 Aug 2020 22:35:41
	System	20 Aug 2020 22:35:41

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T17:35:40', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0fd3bd4a-a4c0-40a0-a07b-272a5cb031e5' User entered '20 Aug 2020 17:35'	System	20 Aug 2020 22:35:41
	System	20 Aug 2020 22:35:41

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 17:19'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 19:49'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:47:26', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '59a67b16-494b-406a-86db-7728c2a90282' User entered 'None (0)'	System	21 Aug 2020 01:48:22
	System	21 Aug 2020 01:48:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:47:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '59a67b16-494b-406a-86db-7728c2a90282' User entered 'None (0)'	System	21 Aug 2020 01:48:22
	System	21 Aug 2020 01:48:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:47:51', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '59a67b16-494b-406a-86db-7728c2a90282' User entered 'None (0)'	System	21 Aug 2020 01:48:22
	System	21 Aug 2020 01:48:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:48:04', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '59a67b16-494b-406a-86db-7728c2a90282' User entered 'None (0)'	System	21 Aug 2020 01:48:22
	System	21 Aug 2020 01:48:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:48:06', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '59a67b16-494b-406a-86db-7728c2a90282' User entered 'None (0)'	System	21 Aug 2020 01:48:22
	System	21 Aug 2020 01:48:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:48:10', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '59a67b16-494b-406a-86db-7728c2a90282' User entered 'None (0)'	System	21 Aug 2020 01:48:22
	System	21 Aug 2020 01:48:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:48:13', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '59a67b16-494b-406a-86db-7728c2a90282'	System	21 Aug 2020 01:48:22
User entered 'No (N)'	System	21 Aug 2020 01:48:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-20T20:48:18', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '59a67b16-494b-406a-86db-7728c2a90282' User entered '20 Aug 2020 20:48'	System	21 Aug 2020 01:48:22
	System	21 Aug 2020 01:48:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Aug 2020 20:44'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 2'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:20:36', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '86330dcc-483d-4da0-b576-dfa5777b9dce' User entered 'None (0)'	System	21 Aug 2020 19:22:08
	System	21 Aug 2020 19:22:08

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:20:51', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '86330dcc-483d-4da0-b576-dfa5777b9dce' User entered 'None (0)'	System	21 Aug 2020 19:22:08
	System	21 Aug 2020 19:22:08

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:21:01', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '86330dcc-483d-4da0-b576-dfa5777b9dce' User entered 'Some interference with activity (2)'	System	21 Aug 2020 19:22:08
	System	21 Aug 2020 19:22:08

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:21:07', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '86330dcc-483d-4da0-b576-dfa5777b9dce' User entered 'None (0)'	System	21 Aug 2020 19:22:08
	System	21 Aug 2020 19:22:08

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:21:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '86330dcc-483d-4da0-b576-dfa5777b9dce'	System	21 Aug 2020 19:22:08
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	21 Aug 2020 19:22:08

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:21:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '86330dcc-483d-4da0-b576-dfa5777b9dce' User entered 'None (0)'	System	21 Aug 2020 19:22:08
	System	21 Aug 2020 19:22:08

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:22:03', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '86330dcc-483d-4da0-b576-dfa5777b9dce' User entered 'No (N)'	System	21 Aug 2020 19:22:08
	System	21 Aug 2020 19:22:08

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-21T14:22:06', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '86330dcc-483d-4da0-b576-dfa5777b9dce' User entered '21 Aug 2020 14:22'	System	21 Aug 2020 19:22:08
	System	21 Aug 2020 19:22:08

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 3'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:06', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2a5aecb-87c9-471f-9351-a3428dfacc03' User entered 'None (0)'	System	22 Aug 2020 18:41:30
	System	22 Aug 2020 18:41:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:08', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2a5aecb-87c9-471f-9351-a3428dfacc03' User entered 'None (0)'	System	22 Aug 2020 18:41:30
	System	22 Aug 2020 18:41:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:11', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2a5aecb-87c9-471f-9351-a3428dfacc03' User entered 'None (0)'	System	22 Aug 2020 18:41:30
	System	22 Aug 2020 18:41:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:13', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2a5aecb-87c9-471f-9351-a3428dfacc03' User entered 'None (0)'	System	22 Aug 2020 18:41:30
	System	22 Aug 2020 18:41:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:16', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2a5aecb-87c9-471f-9351-a3428dfacc03' User entered 'None (0)'	System	22 Aug 2020 18:41:30
	System	22 Aug 2020 18:41:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:18', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2a5aecb-87c9-471f-9351-a3428dfacc03' User entered 'None (0)'	System	22 Aug 2020 18:41:30
	System	22 Aug 2020 18:41:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:22', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2a5aecb-87c9-471f-9351-a3428dfacc03'	System	22 Aug 2020 18:41:30
User entered 'No (N)'	System	22 Aug 2020 18:41:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-22T13:41:27', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a2a5aecb-87c9-471f-9351-a3428dfacc03' User entered '22 Aug 2020 13:41'	System	22 Aug 2020 18:41:30
	System	22 Aug 2020 18:41:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 4'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:46:20', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '33357fcd-b7a-4df9-adb6-a80409b778ee' User entered 'None (0)'	System	23 Aug 2020 22:47:30
	System	23 Aug 2020 22:47:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:46:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '33357fcd-b7a-4df9-adb6-a80409b778ee' User entered 'None (0)'	System	23 Aug 2020 22:47:30
	System	23 Aug 2020 22:47:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:46:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '33357fcd-b7a-4df9-adb6-a80409b778ee'	System	23 Aug 2020 22:47:30
User entered 'Some interference with activity (2)'	System	23 Aug 2020 22:47:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:47:04', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '33357fcd-b7a-4df9-adb6-a80409b778ee'	System	23 Aug 2020 22:47:30
User entered 'Some interference with activity (2)'	System	23 Aug 2020 22:47:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:47:08', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '33357fcd-b7a-4df9-adb6-a80409b778ee' User entered 'None (0)'	System	23 Aug 2020 22:47:30
	System	23 Aug 2020 22:47:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:47:18', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '33357fcd-b7a-4df9-adb6-a80409b778ee'	System	23 Aug 2020 22:47:30
User entered 'No interference with activity (1)'	System	23 Aug 2020 22:47:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:47:22', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '33357fcd-b7a-4df9-adb6-a80409b778ee' User entered 'No (N)'	System	23 Aug 2020 22:47:30
	System	23 Aug 2020 22:47:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-23T17:47:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '33357fcd-b7a-4df9-adb6-a80409b778ee' User entered '23 Aug 2020 17:47'	System	23 Aug 2020 22:47:30
	System	23 Aug 2020 22:47:30

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 5'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:29:36', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2e17bfa6-b159-4662-a7e4-cc2755de7ac0' User entered 'None (0)'	System	24 Aug 2020 22:29:42
	System	24 Aug 2020 22:29:42

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:28:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2e17bfa6-b159-4662-a7e4-cc2755de7ac0' User entered 'None (0)'	System	24 Aug 2020 22:29:42
	System	24 Aug 2020 22:29:42

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:29:02', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2e17bfa6-b159-4662-a7e4-cc2755de7ac0' User entered 'None (0)'	System	24 Aug 2020 22:29:42
	System	24 Aug 2020 22:29:42

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:29:04', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2e17bfa6-b159-4662-a7e4-cc2755de7ac0' User entered 'None (0)'	System	24 Aug 2020 22:29:42
	System	24 Aug 2020 22:29:42

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:29:06', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2e17bfa6-b159-4662-a7e4-cc2755de7ac0' User entered 'None (0)'	System	24 Aug 2020 22:29:42
	System	24 Aug 2020 22:29:42

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:29:10', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2e17bfa6-b159-4662-a7e4-cc2755de7ac0' User entered 'None (0)'	System	24 Aug 2020 22:29:42
	System	24 Aug 2020 22:29:42

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:29:13', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2e17bfa6-b159-4662-a7e4-cc2755de7ac0'	System	24 Aug 2020 22:29:42
User entered 'No (N)'	System	24 Aug 2020 22:29:42

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-24T17:29:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2e17bfa6-b159-4662-a7e4-cc2755de7ac0' User entered '24 Aug 2020 17:29'	System	24 Aug 2020 22:29:42
	System	24 Aug 2020 22:29:42

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 6'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:35', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2ecd9f1b-609d-4153-900d-f37d0fe4034d' User entered 'None (0)'	System	25 Aug 2020 19:05:17
	System	25 Aug 2020 19:05:17

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2ecd9f1b-609d-4153-900d-f37d0fe4034d' User entered 'None (0)'	System	25 Aug 2020 19:05:17
	System	25 Aug 2020 19:05:17

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:40', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2ecd9f1b-609d-4153-900d-f37d0fe4034d' User entered 'None (0)'	System	25 Aug 2020 19:05:17
	System	25 Aug 2020 19:05:17

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:42', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2ecd9f1b-609d-4153-900d-f37d0fe4034d' User entered 'None (0)'	System	25 Aug 2020 19:05:17
	System	25 Aug 2020 19:05:17

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2ecd9f1b-609d-4153-900d-f37d0fe4034d' User entered 'None (0)'	System	25 Aug 2020 19:05:17
	System	25 Aug 2020 19:05:17

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2ecd9f1b-609d-4153-900d-f37d0fe4034d' User entered 'None (0)'	System	25 Aug 2020 19:05:17
	System	25 Aug 2020 19:05:17

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:49', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2ecd9f1b-609d-4153-900d-f37d0fe4034d' User entered 'No (N)'	System	25 Aug 2020 19:05:17
	System	25 Aug 2020 19:05:17

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-25T14:04:53', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '2ecd9f1b-609d-4153-900d-f37d0fe4034d' User entered '25 Aug 2020 14:04'	System	25 Aug 2020 19:05:17
	System	25 Aug 2020 19:05:17

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 7'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:17', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c35c059e-ce72-4ea3-a0a6-de07f50efe5f' User entered 'None (0)'	System	26 Aug 2020 18:01:58
	System	26 Aug 2020 18:01:58

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:19', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c35c059e-ce72-4ea3-a0a6-de07f50efe5f' User entered 'None (0)'	System	26 Aug 2020 18:01:58
	System	26 Aug 2020 18:01:58

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:35', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c35c059e-ce72-4ea3-a0a6-de07f50efe5f' User entered 'None (0)'	System	26 Aug 2020 18:01:58
	System	26 Aug 2020 18:01:58

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c35c059e-ce72-4ea3-a0a6-de07f50efe5f' User entered 'None (0)'	System	26 Aug 2020 18:01:58
	System	26 Aug 2020 18:01:58

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c35c059e-ce72-4ea3-a0a6-de07f50efe5f' User entered 'None (0)'	System	26 Aug 2020 18:01:58
	System	26 Aug 2020 18:01:58

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:47', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c35c059e-ce72-4ea3-a0a6-de07f50efe5f' User entered 'None (0)'	System	26 Aug 2020 18:01:58
	System	26 Aug 2020 18:01:58

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:50', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c35c059e-ce72-4ea3-a0a6-de07f50efe5f' User entered 'No (N)'	System	26 Aug 2020 18:01:58
	System	26 Aug 2020 18:01:58

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-08-26T13:01:53', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c35c059e-ce72-4ea3-a0a6-de07f50efe5f' User entered '26 Aug 2020 13:01'	System	26 Aug 2020 18:01:58
	System	26 Aug 2020 18:01:58

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 22:05:22

US3292259

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	29 Aug 2020 16:07:28

US3292259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Aug 2020'	(b) (4) Kristy Trevino (b) (4)	29 Aug 2020 16:07:28

US3292259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	29 Aug 2020 16:07:28

US3292259

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	29 Aug 2020 16:07:28

US3292259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	29 Aug 2020 16:07:38

US3292259

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'l'	System	29 Aug 2020 16:07:38

US3292259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:58:40

US3292259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '5 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:58:40

US3292259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:58:40

US3292259

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:58:40

US3292259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	05 Sep 2020 19:58:44

US3292259

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'l'	System	05 Sep 2020 19:58:44

US3292259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	11 Sep 2020 22:18:52

US3292259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '11 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	11 Sep 2020 22:18:52

US3292259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	11 Sep 2020 22:18:52

US3292259

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	11 Sep 2020 22:18:52

US3292259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	11 Sep 2020 22:19:05

US3292259

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'l'	System	11 Sep 2020 22:19:05

US3292259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:18:25

US3292259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:18:25

US3292259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	17 Sep 2020 20:18:25

US3292259

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'VISIT2'	System	17 Sep 2020 20:18:25

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User accepted default value 'Pre-Dose (PREDOSE)'		17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '09:27'	(b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '17 Sep 2020 09:27'	System	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '37.0' C	(b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '71'	(b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'bpm'	System	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '16'	(b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'breaths/min'	System	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '125'	(b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '84'	(b) (4), (b) (6)	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	17 Sep 2020 20:19:16

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User accepted default value 'Post-Dose (POSTDOSE)'		17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '12:07'	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '17 Sep 2020 12:07'	System	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '36.8' C	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Oral (Oral)'	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '65'	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'bpm'	System	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '16'	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'breaths/min'	System	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '117'	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '76'	(b) (4), (b) (6)	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	17 Sep 2020 20:20:07

US3292259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:20:24

US3292259

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:20:24

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:20:50

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:20:50

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Urine (URINE)'	(b) (4), (b) (6)	17 Sep 2020 20:20:50

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Negative (NEGATIVE)'	(b) (4), (b) (6)	17 Sep 2020 20:20:50

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4), (b) (6)	17 Sep 2020 20:20:50

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:20:50

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '09:23'	(b) (4), (b) (6)	17 Sep 2020 20:20:50

US3292259

Folder: Visit 2 Day 29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '17 Sep 2020 09:23'	System	17 Sep 2020 20:20:50

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '11:37'	(b) (4), (b) (6)	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '17 Sep 2020 11:37'	System	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'ONCE'	System	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 17:06:36

US3292259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:21:05

US3292259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:21:05

US3292259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '09:44'	(b) (4), (b) (6)	17 Sep 2020 20:21:05

US3292259

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '17 Sep 2020 09:44'	System	17 Sep 2020 20:21:05

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '17 Sep 2020'	(b) (4), (b) (6)	17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '10:10'	(b) (4), (b) (6)	17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '17 Sep 2020 10:10'	System	17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:39

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered empty.	System	17 Sep 2020 20:21:19

US3292259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 20:21:23

US3292259

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'l'	System	17 Sep 2020 20:21:23

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:10:20', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a041d762-7d39-4a0b-9ef6-5d0a41487b82' User entered 'Yes (Y)'	System	17 Sep 2020 17:10:37
	System	17 Sep 2020 17:10:37

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:10:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a041d762-7d39-4a0b-9ef6-5d0a41487b82' User entered '98.2'	System	17 Sep 2020 17:10:37
	System	17 Sep 2020 17:10:37

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:10:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a041d762-7d39-4a0b-9ef6-5d0a41487b82'	System	17 Sep 2020 17:10:37
User entered 'No (N)'	System	17 Sep 2020 17:10:37

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:10:34', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a041d762-7d39-4a0b-9ef6-5d0a41487b82' User entered '17 Sep 2020 12:10'	System	17 Sep 2020 17:10:37
	System	17 Sep 2020 17:10:37

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 11:57'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 14:27'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:40:21', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '378f70b8-96cd-4550-acf8-ecf67a70289c' User entered 'Yes (Y)'	System	18 Sep 2020 08:40:44
	System	18 Sep 2020 08:40:44

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:40:26', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '378f70b8-96cd-4550-acf8-ecf67a70289c' User entered '97.2'	System	18 Sep 2020 08:40:44
	System	18 Sep 2020 08:40:44

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:40:35', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '378f70b8-96cd-4550-acf8-ecf67a70289c' User entered 'No (N)'	System	18 Sep 2020 08:40:44
	System	18 Sep 2020 08:40:44

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:40:40', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '378f70b8-96cd-4550-acf8-ecf67a70289c' User entered '18 Sep 2020 03:40'	System	18 Sep 2020 08:40:44
	System	18 Sep 2020 08:40:44

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 15:22'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 2'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:03:05', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a621e5e6-bda5-4f36-af3d-1230759f7f03' User entered 'Yes (Y)'	System	18 Sep 2020 17:03:55
	System	18 Sep 2020 17:03:55

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:02:04', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a621e5e6-bda5-4f36-af3d-1230759f7f03' User entered '98.2'	System	18 Sep 2020 17:03:55
	System	18 Sep 2020 17:03:55

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:03:32', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a621e5e6-bda5-4f36-af3d-1230759f7f03'	System	18 Sep 2020 17:03:55
User entered 'No (N)'	System	18 Sep 2020 17:03:55

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:03:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a621e5e6-bda5-4f36-af3d-1230759f7f03' User entered '18 Sep 2020 12:03'	System	18 Sep 2020 17:03:55
	System	18 Sep 2020 17:03:55

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 3'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:46:45', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ce7ee538-dc95-4910-9caa-4aa7fcec60e8' User entered 'Yes (Y)'	System	19 Sep 2020 17:47:02
	System	19 Sep 2020 17:47:02

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:46:49', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ce7ee538-dc95-4910-9caa-4aa7fcec60e8' User entered '98.3'	System	19 Sep 2020 17:47:02
	System	19 Sep 2020 17:47:02

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:46:52', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ce7ee538-dc95-4910-9caa-4aa7fcec60e8' User entered 'No (N)'	System	19 Sep 2020 17:47:02
	System	19 Sep 2020 17:47:02

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:46:57', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ce7ee538-dc95-4910-9caa-4aa7fcec60e8' User entered '19 Sep 2020 12:46'	System	19 Sep 2020 17:47:02
	System	19 Sep 2020 17:47:02

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 4'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:49:58', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'd459a64f-c642-45e4-9c50-9a3182c2818e' User entered 'Yes (Y)'	System	21 Sep 2020 11:50:09
	System	21 Sep 2020 11:50:09

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:02', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'd459a64f-c642-45e4-9c50-9a3182c2818e' User entered '97.7'	System	21 Sep 2020 11:50:09
	System	21 Sep 2020 11:50:09

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:04', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'd459a64f-c642-45e4-9c50-9a3182c2818e' User entered 'No (N)'	System	21 Sep 2020 11:50:09
	System	21 Sep 2020 11:50:09

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:08', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'd459a64f-c642-45e4-9c50-9a3182c2818e' User entered '21 Sep 2020 06:50'	System	21 Sep 2020 11:50:09
	System	21 Sep 2020 11:50:09

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 5'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:05', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd1eb462-79c2-4aaa-aead-90f6fa382066' User entered 'Yes (Y)'	System	21 Sep 2020 17:05:22
	System	21 Sep 2020 17:05:22

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:08', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd1eb462-79c2-4aaa-aead-90f6fa382066' User entered '97.2'	System	21 Sep 2020 17:05:22
	System	21 Sep 2020 17:05:22

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:11', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd1eb462-79c2-4aaa-aead-90f6fa382066'	System	21 Sep 2020 17:05:22
User entered 'No (N)'	System	21 Sep 2020 17:05:22

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:17', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd1eb462-79c2-4aaa-aead-90f6fa382066' User entered '21 Sep 2020 12:02'	System	21 Sep 2020 17:05:22
	System	21 Sep 2020 17:05:22

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 6'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:01:39', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '29810ab7-06d5-4a15-a55d-42f1aa613662'	System	22 Sep 2020 17:03:38
User entered 'Yes (Y)'	System	22 Sep 2020 17:03:38

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:01:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '29810ab7-06d5-4a15-a55d-42f1aa613662' User entered '96.2'	System	22 Sep 2020 17:03:38
	System	22 Sep 2020 17:03:38

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:01:47', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '29810ab7-06d5-4a15-a55d-42f1aa613662'	System	22 Sep 2020 17:03:38
User entered 'No (N)'	System	22 Sep 2020 17:03:38

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:01:51', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '29810ab7-06d5-4a15-a55d-42f1aa613662' User entered '22 Sep 2020 12:01'	System	22 Sep 2020 17:03:38
	System	22 Sep 2020 17:03:38

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 7'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:06', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'e00c5815-5982-4200-b017-1ef10b7bc922'	System	23 Sep 2020 20:17:20
User entered 'Yes (Y)'	System	23 Sep 2020 20:17:20

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:10', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'e00c5815-5982-4200-b017-1ef10b7bc922' User entered '95.1'	System	23 Sep 2020 20:17:20
	System	23 Sep 2020 20:17:20

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:13', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'e00c5815-5982-4200-b017-1ef10b7bc922'	System	23 Sep 2020 20:17:20
User entered 'No (N)'	System	23 Sep 2020 20:17:20

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:16', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'e00c5815-5982-4200-b017-1ef10b7bc922'	System	23 Sep 2020 20:17:20
User entered '23 Sep 2020 15:17'	System	23 Sep 2020 20:17:20

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:10:56', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '074db82d-56ee-44a9-b978-ef7febe30b4f' User entered 'None (1)'	System	17 Sep 2020 17:11:12
	System	17 Sep 2020 17:11:12

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:10:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '074db82d-56ee-44a9-b978-ef7febe30b4f' User entered 'No (N)'	System	17 Sep 2020 17:11:12
	System	17 Sep 2020 17:11:12

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:01', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '074db82d-56ee-44a9-b978-ef7febe30b4f' User entered 'No (N)'	System	17 Sep 2020 17:11:12
	System	17 Sep 2020 17:11:12

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:04', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '074db82d-56ee-44a9-b978-ef7febe30b4f' User entered 'None (1)'	System	17 Sep 2020 17:11:12
	System	17 Sep 2020 17:11:12

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:09', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '074db82d-56ee-44a9-b978-ef7febe30b4f' User entered '17 Sep 2020 12:11'	System	17 Sep 2020 17:11:12
	System	17 Sep 2020 17:11:12

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 11:57'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 14:27'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:04', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c6030320-2ab7-410c-9b9b-6de25c7ac5ab' User entered 'None (1)'	System	18 Sep 2020 08:41:09
	System	18 Sep 2020 08:41:09

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:40:50', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c6030320-2ab7-410c-9b9b-6de25c7ac5ab' User entered 'No (N)'	System	18 Sep 2020 08:41:09
	System	18 Sep 2020 08:41:09

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:40:54', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c6030320-2ab7-410c-9b9b-6de25c7ac5ab' User entered 'No (N)'	System	18 Sep 2020 08:41:09
	System	18 Sep 2020 08:41:09

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:40:58', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c6030320-2ab7-410c-9b9b-6de25c7ac5ab' User entered 'None (1)'	System	18 Sep 2020 08:41:09
	System	18 Sep 2020 08:41:09

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:06', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c6030320-2ab7-410c-9b9b-6de25c7ac5ab' User entered '18 Sep 2020 03:41'	System	18 Sep 2020 08:41:09
	System	18 Sep 2020 08:41:09

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 15:22'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 2'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:14', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '89580308-8789-41d8-96c1-ada9567672f2'	System	18 Sep 2020 17:04:20
User entered 'None (1)'	System	18 Sep 2020 17:04:20

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:03:48', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '89580308-8789-41d8-96c1-ada9567672f2'	System	18 Sep 2020 17:04:20
User entered 'No (N)'	System	18 Sep 2020 17:04:20

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:03:51', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '89580308-8789-41d8-96c1-ada9567672f2'	System	18 Sep 2020 17:04:20
User entered 'No (N)'	System	18 Sep 2020 17:04:20

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:03:54', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '89580308-8789-41d8-96c1-ada9567672f2'	System	18 Sep 2020 17:04:20
User entered 'None (1)'	System	18 Sep 2020 17:04:20

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:17', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '89580308-8789-41d8-96c1-ada9567672f2' User entered '18 Sep 2020 12:04'	System	18 Sep 2020 17:04:20
	System	18 Sep 2020 17:04:20

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 3'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:23', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f31903ba-9494-460c-a086-864c17ead2f3' User entered 'None (1)'	System	19 Sep 2020 17:47:29
	System	19 Sep 2020 17:47:29

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:11', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f31903ba-9494-460c-a086-864c17ead2f3' User entered 'No (N)'	System	19 Sep 2020 17:47:29
	System	19 Sep 2020 17:47:29

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:15', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f31903ba-9494-460c-a086-864c17ead2f3'	System	19 Sep 2020 17:47:29
User entered 'No (N)'	System	19 Sep 2020 17:47:29

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:18', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f31903ba-9494-460c-a086-864c17ead2f3' User entered 'None (1)'	System	19 Sep 2020 17:47:29
	System	19 Sep 2020 17:47:29

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f31903ba-9494-460c-a086-864c17ead2f3' User entered '19 Sep 2020 12:47'	System	19 Sep 2020 17:47:29
	System	19 Sep 2020 17:47:29

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 4'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:13', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c092a7a7-797f-497d-9bd0-7be5ee01131d' User entered 'None (1)'	System	21 Sep 2020 11:50:28
	System	21 Sep 2020 11:50:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:15', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c092a7a7-797f-497d-9bd0-7be5ee01131d' User entered 'No (N)'	System	21 Sep 2020 11:50:28
	System	21 Sep 2020 11:50:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:18', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c092a7a7-797f-497d-9bd0-7be5ee01131d' User entered 'No (N)'	System	21 Sep 2020 11:50:28
	System	21 Sep 2020 11:50:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:21', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c092a7a7-797f-497d-9bd0-7be5ee01131d' User entered 'None (1)'	System	21 Sep 2020 11:50:28
	System	21 Sep 2020 11:50:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:26', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c092a7a7-797f-497d-9bd0-7be5ee01131d' User entered '21 Sep 2020 06:50'	System	21 Sep 2020 11:50:28
	System	21 Sep 2020 11:50:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 5'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:21', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '05fbbf78-2e7a-4bb7-aad3-d851537597ae'	System	21 Sep 2020 17:05:39
User entered 'None (1)'	System	21 Sep 2020 17:05:39

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:24', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '05fbbf78-2e7a-4bb7-aad3-d851537597ae' User entered 'No (N)'	System	21 Sep 2020 17:05:39
	System	21 Sep 2020 17:05:39

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:26', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '05fbbf78-2e7a-4bb7-aad3-d851537597ae' User entered 'No (N)'	System	21 Sep 2020 17:05:39
	System	21 Sep 2020 17:05:39

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '05fbbf78-2e7a-4bb7-aad3-d851537597ae' User entered 'None (1)'	System	21 Sep 2020 17:05:39
	System	21 Sep 2020 17:05:39

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:34', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '05fbbf78-2e7a-4bb7-aad3-d851537597ae' User entered '21 Sep 2020 12:02'	System	21 Sep 2020 17:05:39
	System	21 Sep 2020 17:05:39

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 6'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:01:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5b1f703f-7bcd-414d-9a75-8bd9e5a29f47'	System	22 Sep 2020 17:04:28
User entered 'None (1)'	System	22 Sep 2020 17:04:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:01:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5b1f703f-7bcd-414d-9a75-8bd9e5a29f47'	System	22 Sep 2020 17:04:28
User entered 'No (N)'	System	22 Sep 2020 17:04:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:02:05', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5b1f703f-7bcd-414d-9a75-8bd9e5a29f47'	System	22 Sep 2020 17:04:28
User entered 'No (N)'	System	22 Sep 2020 17:04:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:02:09', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5b1f703f-7bcd-414d-9a75-8bd9e5a29f47'	System	22 Sep 2020 17:04:28
User entered 'None (1)'	System	22 Sep 2020 17:04:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:02:11', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5b1f703f-7bcd-414d-9a75-8bd9e5a29f47' User entered '22 Sep 2020 12:02'	System	22 Sep 2020 17:04:28
	System	22 Sep 2020 17:04:28

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 7'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:21', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a9dd999c-d926-4f5f-95f0-2e4a882ff855'	System	23 Sep 2020 20:17:37
User entered 'None (1)'	System	23 Sep 2020 20:17:37

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a9dd999c-d926-4f5f-95f0-2e4a882ff855'	System	23 Sep 2020 20:17:37
User entered 'No (N)'	System	23 Sep 2020 20:17:37

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a9dd999c-d926-4f5f-95f0-2e4a882ff855'	System	23 Sep 2020 20:17:37
User entered 'No (N)'	System	23 Sep 2020 20:17:37

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

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 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:30', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a9dd999c-d926-4f5f-95f0-2e4a882ff855'	System	23 Sep 2020 20:17:37
User entered 'None (1)'	System	23 Sep 2020 20:17:37

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:34', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a9dd999c-d926-4f5f-95f0-2e4a882ff855'	System	23 Sep 2020 20:17:37
User entered '23 Sep 2020 15:17'	System	23 Sep 2020 20:17:37

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:13', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f504b910-d483-4fcc-af92-51d303d1a804' User entered 'None (0)'	System	17 Sep 2020 17:11:30
	System	17 Sep 2020 17:11:30

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:15', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f504b910-d483-4fcc-af92-51d303d1a804' User entered 'None (0)'	System	17 Sep 2020 17:11:30
	System	17 Sep 2020 17:11:30

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:17', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f504b910-d483-4fcc-af92-51d303d1a804' User entered 'None (0)'	System	17 Sep 2020 17:11:30
	System	17 Sep 2020 17:11:30

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:19', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f504b910-d483-4fcc-af92-51d303d1a804' User entered 'None (0)'	System	17 Sep 2020 17:11:30
	System	17 Sep 2020 17:11:30

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:20', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f504b910-d483-4fcc-af92-51d303d1a804' User entered 'None (0)'	System	17 Sep 2020 17:11:30
	System	17 Sep 2020 17:11:30

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:22', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f504b910-d483-4fcc-af92-51d303d1a804' User entered 'None (0)'	System	17 Sep 2020 17:11:30
	System	17 Sep 2020 17:11:30

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:24', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f504b910-d483-4fcc-af92-51d303d1a804'	System	17 Sep 2020 17:11:30
User entered 'No (N)'	System	17 Sep 2020 17:11:30

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-17T12:11:27', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f504b910-d483-4fcc-af92-51d303d1a804' User entered '17 Sep 2020 12:11'	System	17 Sep 2020 17:11:30
	System	17 Sep 2020 17:11:30

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 11:57'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 14:27'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:11', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '74604a39-cea9-4cb5-a2e8-ffac45e1f5a6'	System	18 Sep 2020 08:41:42
User entered 'None (0)'	System	18 Sep 2020 08:41:42

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:14', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '74604a39-cea9-4cb5-a2e8-ffac45e1f5a6' User entered 'None (0)'	System	18 Sep 2020 08:41:42
	System	18 Sep 2020 08:41:42

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:17', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '74604a39-cea9-4cb5-a2e8-ffac45e1f5a6' User entered 'None (0)'	System	18 Sep 2020 08:41:42
	System	18 Sep 2020 08:41:42

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:20', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '74604a39-cea9-4cb5-a2e8-ffac45e1f5a6' User entered 'None (0)'	System	18 Sep 2020 08:41:42
	System	18 Sep 2020 08:41:42

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:22', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '74604a39-cea9-4cb5-a2e8-ffac45e1f5a6' User entered 'None (0)'	System	18 Sep 2020 08:41:42
	System	18 Sep 2020 08:41:42

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '74604a39-cea9-4cb5-a2e8-ffac45e1f5a6' User entered 'None (0)'	System	18 Sep 2020 08:41:42
	System	18 Sep 2020 08:41:42

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:31', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '74604a39-cea9-4cb5-a2e8-ffac45e1f5a6'	System	18 Sep 2020 08:41:42
User entered 'No (N)'	System	18 Sep 2020 08:41:42

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T03:41:37', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '74604a39-cea9-4cb5-a2e8-ffac45e1f5a6' User entered '18 Sep 2020 03:41'	System	18 Sep 2020 08:41:42
	System	18 Sep 2020 08:41:42

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '17 Sep 2020 15:22'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 2'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:24', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '883ac58c-5e52-422e-88e8-6642b1067a5a' User entered 'None (0)'	System	18 Sep 2020 17:04:50
	System	18 Sep 2020 17:04:50

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:26', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '883ac58c-5e52-422e-88e8-6642b1067a5a' User entered 'None (0)'	System	18 Sep 2020 17:04:50
	System	18 Sep 2020 17:04:50

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '883ac58c-5e52-422e-88e8-6642b1067a5a' User entered 'None (0)'	System	18 Sep 2020 17:04:50
	System	18 Sep 2020 17:04:50

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:32', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '883ac58c-5e52-422e-88e8-6642b1067a5a' User entered 'None (0)'	System	18 Sep 2020 17:04:50
	System	18 Sep 2020 17:04:50

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:35', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '883ac58c-5e52-422e-88e8-6642b1067a5a' User entered 'None (0)'	System	18 Sep 2020 17:04:50
	System	18 Sep 2020 17:04:50

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:37', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '883ac58c-5e52-422e-88e8-6642b1067a5a' User entered 'None (0)'	System	18 Sep 2020 17:04:50
	System	18 Sep 2020 17:04:50

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:42', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '883ac58c-5e52-422e-88e8-6642b1067a5a' User entered 'No (N)'	System	18 Sep 2020 17:04:50
	System	18 Sep 2020 17:04:50

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-18T12:04:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '883ac58c-5e52-422e-88e8-6642b1067a5a' User entered '18 Sep 2020 12:04'	System	18 Sep 2020 17:04:50
	System	18 Sep 2020 17:04:50

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 3'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:48', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c4887365-932a-4a8b-bc9a-09a85f93059f' User entered 'None (0)'	System	19 Sep 2020 17:47:55
	System	19 Sep 2020 17:47:55

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:32', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c4887365-932a-4a8b-bc9a-09a85f93059f' User entered 'None (0)'	System	19 Sep 2020 17:47:55
	System	19 Sep 2020 17:47:55

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:34', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c4887365-932a-4a8b-bc9a-09a85f93059f' User entered 'None (0)'	System	19 Sep 2020 17:47:55
	System	19 Sep 2020 17:47:55

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:36', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c4887365-932a-4a8b-bc9a-09a85f93059f' User entered 'None (0)'	System	19 Sep 2020 17:47:55
	System	19 Sep 2020 17:47:55

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c4887365-932a-4a8b-bc9a-09a85f93059f' User entered 'None (0)'	System	19 Sep 2020 17:47:55
	System	19 Sep 2020 17:47:55

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:40', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c4887365-932a-4a8b-bc9a-09a85f93059f' User entered 'None (0)'	System	19 Sep 2020 17:47:55
	System	19 Sep 2020 17:47:55

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:44', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c4887365-932a-4a8b-bc9a-09a85f93059f' User entered 'No (N)'	System	19 Sep 2020 17:47:55
	System	19 Sep 2020 17:47:55

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-19T12:47:51', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c4887365-932a-4a8b-bc9a-09a85f93059f' User entered '19 Sep 2020 12:47'	System	19 Sep 2020 17:47:55
	System	19 Sep 2020 17:47:55

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 4'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c0345a76-5661-4f24-b556-4deca1bb74ba' User entered 'None (0)'	System	21 Sep 2020 11:50:48
	System	21 Sep 2020 11:50:48

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:31', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c0345a76-5661-4f24-b556-4deca1bb74ba' User entered 'None (0)'	System	21 Sep 2020 11:50:48
	System	21 Sep 2020 11:50:48

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:33', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c0345a76-5661-4f24-b556-4deca1bb74ba' User entered 'None (0)'	System	21 Sep 2020 11:50:48
	System	21 Sep 2020 11:50:48

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:35', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c0345a76-5661-4f24-b556-4deca1bb74ba' User entered 'None (0)'	System	21 Sep 2020 11:50:48
	System	21 Sep 2020 11:50:48

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:37', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c0345a76-5661-4f24-b556-4deca1bb74ba' User entered 'None (0)'	System	21 Sep 2020 11:50:48
	System	21 Sep 2020 11:50:48

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:39', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c0345a76-5661-4f24-b556-4deca1bb74ba' User entered 'None (0)'	System	21 Sep 2020 11:50:48
	System	21 Sep 2020 11:50:48

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:42', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c0345a76-5661-4f24-b556-4deca1bb74ba' User entered 'No (N)'	System	21 Sep 2020 11:50:48
	System	21 Sep 2020 11:50:48

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T06:50:45', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c0345a76-5661-4f24-b556-4deca1bb74ba' User entered '21 Sep 2020 06:50'	System	21 Sep 2020 11:50:48
	System	21 Sep 2020 11:50:48

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 5'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:37', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dbfb3661-7b45-4f5b-b61c-0b3f13aa6952' User entered 'None (0)'	System	21 Sep 2020 17:05:58
	System	21 Sep 2020 17:05:58

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:41', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dbfb3661-7b45-4f5b-b61c-0b3f13aa6952' User entered 'None (0)'	System	21 Sep 2020 17:05:58
	System	21 Sep 2020 17:05:58

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dbfb3661-7b45-4f5b-b61c-0b3f13aa6952' User entered 'None (0)'	System	21 Sep 2020 17:05:58
	System	21 Sep 2020 17:05:58

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dbfb3661-7b45-4f5b-b61c-0b3f13aa6952' User entered 'None (0)'	System	21 Sep 2020 17:05:58
	System	21 Sep 2020 17:05:58

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:48', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dbfb3661-7b45-4f5b-b61c-0b3f13aa6952' User entered 'None (0)'	System	21 Sep 2020 17:05:58
	System	21 Sep 2020 17:05:58

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:50', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dbfb3661-7b45-4f5b-b61c-0b3f13aa6952' User entered 'None (0)'	System	21 Sep 2020 17:05:58
	System	21 Sep 2020 17:05:58

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:53', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dbfb3661-7b45-4f5b-b61c-0b3f13aa6952'	System	21 Sep 2020 17:05:58
User entered 'No (N)'	System	21 Sep 2020 17:05:58

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-21T12:02:56', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dbfb3661-7b45-4f5b-b61c-0b3f13aa6952' User entered '21 Sep 2020 12:02'	System	21 Sep 2020 17:05:58
	System	21 Sep 2020 17:05:58

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 6'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:02:48', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'aa55efc5-8f52-4fa1-892f-b961d3ae3b99'	System	22 Sep 2020 17:06:14
User entered 'None (0)'	System	22 Sep 2020 17:06:14

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:02:50', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'aa55efc5-8f52-4fa1-892f-b961d3ae3b99'	System	22 Sep 2020 17:06:14
User entered 'None (0)'	System	22 Sep 2020 17:06:14

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:02:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'aa55efc5-8f52-4fa1-892f-b961d3ae3b99' User entered 'None (0)'	System	22 Sep 2020 17:06:14
	System	22 Sep 2020 17:06:14

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:03:02', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'aa55efc5-8f52-4fa1-892f-b961d3ae3b99' User entered 'None (0)'	System	22 Sep 2020 17:06:14
	System	22 Sep 2020 17:06:14

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:03:05', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'aa55efc5-8f52-4fa1-892f-b961d3ae3b99'	System	22 Sep 2020 17:06:14
User entered 'None (0)'	System	22 Sep 2020 17:06:14

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:03:07', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'aa55efc5-8f52-4fa1-892f-b961d3ae3b99'	System	22 Sep 2020 17:06:14
User entered 'None (0)'	System	22 Sep 2020 17:06:14

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:03:10', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'aa55efc5-8f52-4fa1-892f-b961d3ae3b99'	System	22 Sep 2020 17:06:14
User entered 'No (N)'	System	22 Sep 2020 17:06:14

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-22T12:03:12', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'aa55efc5-8f52-4fa1-892f-b961d3ae3b99'	System	22 Sep 2020 17:06:14
User entered '22 Sep 2020 12:03'	System	22 Sep 2020 17:06:14

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	17 Sep 2020 17:06:36
User entered 'Day 7'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:37', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c136c902-50c5-4605-85c6-9e7e22fbc026' User entered 'None (0)'	System	23 Sep 2020 20:17:56
	System	23 Sep 2020 20:17:56

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:39', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c136c902-50c5-4605-85c6-9e7e22fbc026' User entered 'None (0)'	System	23 Sep 2020 20:17:56
	System	23 Sep 2020 20:17:56

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:41', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c136c902-50c5-4605-85c6-9e7e22fbc026' User entered 'None (0)'	System	23 Sep 2020 20:17:56
	System	23 Sep 2020 20:17:56

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c136c902-50c5-4605-85c6-9e7e22fbc026' User entered 'None (0)'	System	23 Sep 2020 20:17:56
	System	23 Sep 2020 20:17:56

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:44', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c136c902-50c5-4605-85c6-9e7e22fbc026' User entered 'None (0)'	System	23 Sep 2020 20:17:56
	System	23 Sep 2020 20:17:56

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:45', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c136c902-50c5-4605-85c6-9e7e22fbc026' User entered 'None (0)'	System	23 Sep 2020 20:17:56
	System	23 Sep 2020 20:17:56

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:48', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c136c902-50c5-4605-85c6-9e7e22fbc026'	System	23 Sep 2020 20:17:56
User entered 'No (N)'	System	23 Sep 2020 20:17:56

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-09-23T15:17:51', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'c136c902-50c5-4605-85c6-9e7e22fbc026'	System	23 Sep 2020 20:17:56
User entered '23 Sep 2020 15:17'	System	23 Sep 2020 20:17:56

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 17:06:36

US3292259

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 17:06:36

US3292259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	25 Sep 2020 17:51:46

US3292259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '25 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	25 Sep 2020 17:51:46

US3292259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	25 Sep 2020 17:51:46

US3292259

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Kristy Trevino (b) (4)	25 Sep 2020 17:51:46

US3292259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	25 Sep 2020 18:05:01

US3292259

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'l'	System	25 Sep 2020 18:05:01

US3292259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	08 Oct 2020 16:23:49

US3292259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '4 Oct 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	08 Oct 2020 16:23:49

US3292259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	08 Oct 2020 16:23:49

US3292259

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	08 Oct 2020 16:23:49

US3292259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	08 Oct 2020 16:24:10

US3292259

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'I'	System	08 Oct 2020 16:24:10

US3292259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	14 Oct 2020 19:53:48

US3292259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '9 Oct 2020'	(b) (4) Gerardo Pena (b) (4)	14 Oct 2020 19:53:48

US3292259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	14 Oct 2020 19:53:48

US3292259

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	14 Oct 2020 19:53:48

US3292259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	14 Oct 2020 19:54:01

US3292259

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'l'	System	14 Oct 2020 19:54:01

US3292259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:26:51

US3292259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '15 Oct 2020'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:26:51

US3292259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:26:51

US3292259

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'VISIT3'	System	15 Oct 2020 18:26:51

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '15 Oct 2020'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '12:03'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '15 Oct 2020 12:03'	System	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '36.6' C	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '77'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'bpm'	System	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '12'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'breaths/min'	System	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '120'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '81'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'mmHg'	System	15 Oct 2020 18:27:28

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07

US3292259

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07

US3292259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:33

US3292259

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered empty.	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:33

US3292259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:48

US3292259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '15 Oct 2020'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:48

US3292259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered '12:13'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:48

US3292259

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered '15 Oct 2020 12:13'	System	15 Oct 2020 18:27:48

US3292259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:30:46
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Oct 2020 18:27:53

US3292259

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:24:07
User entered 'I'	System	15 Oct 2020 18:27:53

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 64'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-10-20T00:55:47', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '4e79f74e-ed63-41aa-a8d8-4a539048e191'	System	20 Oct 2020 05:56:01
User entered 'No (N)'	System	20 Oct 2020 05:56:01

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-10-20T00:55:53', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '4e79f74e-ed63-41aa-a8d8-4a539048e191'	System	20 Oct 2020 05:56:01
User entered 'No (N)'	System	20 Oct 2020 05:56:01

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-10-20T00:55:58', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '4e79f74e-ed63-41aa-a8d8-4a539048e191' User entered '20 Oct 2020 00:55:58'	System	20 Oct 2020 05:56:01
	System	20 Oct 2020 05:56:01

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 71'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-10-27T03:11:48', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '614ec03f-5f1c-4e57-85ca-31490a768d11' User entered 'No (N)'	System	27 Oct 2020 08:12:02
	System	27 Oct 2020 08:12:02

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-10-27T03:11:53', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '614ec03f-5f1c-4e57-85ca-31490a768d11'	System	27 Oct 2020 08:12:02
User entered 'No (N)'	System	27 Oct 2020 08:12:02

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-10-27T03:11:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '614ec03f-5f1c-4e57-85ca-31490a768d11' User entered '27 Oct 2020 03:11:59'	System	27 Oct 2020 08:12:02
	System	27 Oct 2020 08:12:02

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 78'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-04T10:09:54', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '364fb70e-4cdd-41d8-8578-8026bd62f88d' User entered 'No (N)'	System	04 Nov 2020 16:10:14
	System	04 Nov 2020 16:10:14

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-04T10:10:02', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '364fb70e-4cdd-41d8-8578-8026bd62f88d' User entered 'No (N)'	System	04 Nov 2020 16:10:14
	System	04 Nov 2020 16:10:14

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-04T10:10:09', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '364fb70e-4cdd-41d8-8578-8026bd62f88d' User entered '04 Nov 2020 10:10:09'	System	04 Nov 2020 16:10:14
	System	04 Nov 2020 16:10:14

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 92'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:00:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14'	System	19 Nov 2020 18:02:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:00:53', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14'	System	19 Nov 2020 18:02:07
User entered 'No (N)'	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:00', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14'	System	19 Nov 2020 18:02:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '0'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '0'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '0'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '0'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '0'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
User closed query 'Per DM CLR: Runny Nose was checked and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM). Query 'Per DM CLR: Runny Nose was checked and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'runny nose has been added to AEs' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 13:29:41
User opened query 'Per DM CLR: Runny Nose was checked and Have you contacted a healthcare provider since last questionnaire or study contact? = Yes, however, please note that there is no corresponding AE for this recorded data. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 02:15:33
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14'	System	18 Dec 2020 14:52:29
User entered '1'	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '0'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '1'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:36', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14'	System	19 Nov 2020 18:02:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:44', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14'	System	19 Nov 2020 18:02:07
User entered 'Yes (Y)'	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:50', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14'	System	19 Nov 2020 18:02:07
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-19T12:01:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6fac3f17-61e7-4468-bf37-75b2b7aa1b14' User entered '19 Nov 2020 12:01:55'	System	19 Nov 2020 18:02:07
	System	19 Nov 2020 18:02:07

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
DataPoint activated with code reason code Data required.	Nathan Cortez (b) (4)	20 Nov 2020 16:23:01
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:25
Data entry locked.	System	20 Aug 2020 22:05:22
User entered 'Day 99'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-24T08:51:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5a373a4e-b71a-4e58-8cc0-31cfc897284e' User entered 'No (N)'	System	24 Nov 2020 14:52:07
DataPoint activated with code reason code Data required.	System	24 Nov 2020 14:52:07
Amendment Manager: DataPoint Inactivated.	Nathan Cortez (b) (4)	20 Nov 2020 16:23:01
	System	20 Nov 2020 00:11:25

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-24T08:52:00', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5a373a4e-b71a-4e58-8cc0-31cfc897284e'	System	24 Nov 2020 14:52:07
User entered 'No (N)'	System	24 Nov 2020 14:52:07
DataPoint activated with code reason code Data required.	Nathan Cortez (b) (4)	20 Nov 2020 16:23:01
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:25

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-24T08:52:03', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '5a373a4e-b71a-4e58-8cc0-31cfc897284e' User entered '24 Nov 2020 08:52:03'	System	24 Nov 2020 14:52:07
DataPoint activated with code reason code Data required.	System Nathan Cortez (b) (4)	24 Nov 2020 14:52:07 20 Nov 2020 16:23:01
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:25

US3292259

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
DataPoint activated with code reason code Data required.	Nathan Cortez (b) (4)	20 Nov 2020 16:23:01
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:25
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '24 Nov 2020 00:01'	System	20 Aug 2020 22:05:22

US3292259

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:24:02
DataPoint activated with code reason code Data required.	Nathan Cortez (b) (4)	20 Nov 2020 16:23:01
Amendment Manager: DataPoint Inactivated.	System	20 Nov 2020 00:11:25
Data entry locked.	System	20 Aug 2020 22:05:22
User entered '28 Nov 2020 23:59'	System	20 Aug 2020 22:05:22

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 96'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-21T00:21:18', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'd08b9628-c329-4942-b99c-d04320cf964'	System	21 Nov 2020 06:21:34
User entered 'No (N)'	System	21 Nov 2020 06:21:34

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-21T00:21:26', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'd08b9628-c329-4942-b99c-d04320cf964'	System	21 Nov 2020 06:21:34
User entered 'No (N)'	System	21 Nov 2020 06:21:34

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-21T00:21:30', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'd08b9628-c329-4942-b99c-d04320fcf964'	System	21 Nov 2020 06:21:34
User entered '21 Nov 2020 00:21:30'	System	21 Nov 2020 06:21:34

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '21 Nov 2020 00:01'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '25 Nov 2020 23:59'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 103'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-28T00:50:51', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a7b68fb3-6fa6-46b6-8999-6519d058533e' User entered 'No (N)'	System	29 Nov 2020 01:35:31
	System	29 Nov 2020 01:35:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-28T19:35:21', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a7b68fb3-6fa6-46b6-8999-6519d058533e' User entered 'No (N)'	System	29 Nov 2020 01:35:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-11-28T19:35:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a7b68fb3-6fa6-46b6-8999-6519d058533e' User entered '28 Nov 2020 19:35:28'	System	29 Nov 2020 01:35:31
	System	29 Nov 2020 01:35:31

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '28 Nov 2020 00:01'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '02 Dec 2020 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 110'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-12-05T00:48:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ca8cae20-b33e-4e82-88f3-be8533936321' User entered 'No (N)'	System	05 Dec 2020 06:51:43
	System	05 Dec 2020 06:51:43

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-12-05T00:51:16', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ca8cae20-b33e-4e82-88f3-be8533936321' User entered 'Yes (Y)'	System	05 Dec 2020 06:51:43
	System	05 Dec 2020 06:51:43

US3292259

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.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-12-05T00:51:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ca8cae20-b33e-4e82-88f3-be8533936321'	System	05 Dec 2020 06:51:43
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	05 Dec 2020 06:51:43

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Folder: New Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-12-05T00:51:34', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'ca8cae20-b33e-4e82-88f3-be8533936321' User entered '05 Dec 2020 00:51:34'	System	05 Dec 2020 06:51:43
	System	05 Dec 2020 06:51:43

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '05 Dec 2020 00:01'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '09 Dec 2020 23:59'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 117'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

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[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-12-12T03:25:08', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '433b7736-3459-498a-a739-8c686cb73d20'	System	12 Dec 2020 09:26:02
User entered 'No (N)'	System	12 Dec 2020 09:26:02

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-12-12T03:25:26', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '433b7736-3459-498a-a739-8c686cb73d20'	System	12 Dec 2020 09:26:02
User entered 'No (N)'	System	12 Dec 2020 09:26:02

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (22F94D33-A06E-46EE-BFD2-828B9B2BB0E5)', Time: '2020-12-12T03:25:58', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '433b7736-3459-498a-a739-8c686cb73d20'	System	12 Dec 2020 09:26:02
User entered '12 Dec 2020 03:25:58'	System	12 Dec 2020 09:26:02

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '12 Dec 2020 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '16 Dec 2020 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 124'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2020-12-21T11:55:32', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '20de4dbf-ac78-49f6-b976-bf8efb8e700b' User entered 'No (N)'	System	21 Dec 2020 17:55:43
	System	21 Dec 2020 17:55:43

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2020-12-21T11:55:36', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '20de4dbf-ac78-49f6-b976-bf8efb8e700b' User entered 'No (N)'	System	21 Dec 2020 17:55:43
	System	21 Dec 2020 17:55:43

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2020-12-21T11:55:40', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '20de4dbf-ac78-49f6-b976-bf8efb8e700b' User entered '21 Dec 2020 11:55:40'	System	21 Dec 2020 17:55:43

US3292259

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Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '19 Dec 2020 00:01'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '23 Dec 2020 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 131'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2020-12-26T00:01:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '857755a6-68af-4e94-9ef2-356841d92844' User entered 'No (N)'	System	26 Dec 2020 06:02:03
	System	26 Dec 2020 06:02:03

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2020-12-26T00:01:37', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '857755a6-68af-4e94-9ef2-356841d92844' User entered 'No (N)'	System	26 Dec 2020 06:02:03
	System	26 Dec 2020 06:02:03

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Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2020-12-26T00:01:40', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '857755a6-68af-4e94-9ef2-356841d92844' User entered '26 Dec 2020 00:01:40'	System	26 Dec 2020 06:02:03
	System	26 Dec 2020 06:02:03

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '26 Dec 2020 00:01'	System	20 Nov 2020 00:11:25

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '30 Dec 2020 23:59'	System	20 Nov 2020 00:11:25

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 138'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-02T04:01:01', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '574bef43-3443-4698-88d7-ee7d682dfdd7' User entered 'No (N)'	System	02 Jan 2021 10:01:14
	System	02 Jan 2021 10:01:14

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-02T04:01:07', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '574bef43-3443-4698-88d7-ee7d682dfdd7' User entered 'No (N)'	System	02 Jan 2021 10:01:14
	System	02 Jan 2021 10:01:14

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-02T04:01:11', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '574bef43-3443-4698-88d7-ee7d682dfdd7' User entered '02 Jan 2021 04:01:11'	System	02 Jan 2021 10:01:14
	System	02 Jan 2021 10:01:14

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '02 Jan 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '06 Jan 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 145'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-09T05:26:22', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '83944f49-cb3a-4afe-a243-86d890b4f2f4' User entered 'No (N)'	System	09 Jan 2021 11:26:33
	System	09 Jan 2021 11:26:33

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-09T05:26:12', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '83944f49-cb3a-4afe-a243-86d890b4f2f4' User entered 'No (N)'	System	09 Jan 2021 11:26:33
	System	09 Jan 2021 11:26:33

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-09T05:26:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '83944f49-cb3a-4afe-a243-86d890b4f2f4' User entered '09 Jan 2021 05:26:28'	System	09 Jan 2021 11:26:33
	System	09 Jan 2021 11:26:33

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '09 Jan 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '13 Jan 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 152'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-16T00:52:39', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a58241b5-a3e5-4724-b189-e1c8cb9908eb' User entered 'No (N)'	System	16 Jan 2021 06:52:47
	System	16 Jan 2021 06:52:47

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-16T00:52:32', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a58241b5-a3e5-4724-b189-e1c8cb9908eb' User entered 'No (N)'	System	16 Jan 2021 06:52:47

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-16T00:52:44', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'a58241b5-a3e5-4724-b189-e1c8cb9908eb' User entered '16 Jan 2021 00:52:44'	System	16 Jan 2021 06:52:47
	System	16 Jan 2021 06:52:47

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '16 Jan 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '20 Jan 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 159'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-23T07:22:34', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dae0b913-8c54-4e5a-82d0-e4237e1c5cb6' User entered 'No (N)'	System	25 Jan 2021 16:01:57
	System	25 Jan 2021 16:01:57

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-23T07:22:31', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dae0b913-8c54-4e5a-82d0-e4237e1c5cb6' User entered 'No (N)'	System	25 Jan 2021 16:01:57

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-23T07:22:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'dae0b913-8c54-4e5a-82d0-e4237e1c5cb6' User entered '23 Jan 2021 07:22:43'	System	25 Jan 2021 16:01:57

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '23 Jan 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '27 Jan 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 166'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-30T06:37:24', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '72afb57c-47c5-40a6-af60-4641fcf98b6b' User entered 'No (N)'	System	30 Jan 2021 12:37:36
	System	30 Jan 2021 12:37:36

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-30T06:37:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '72afb57c-47c5-40a6-af60-4641fcf98b6b' User entered 'No (N)'	System	30 Jan 2021 12:37:36

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-01-30T06:37:32', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '72afb57c-47c5-40a6-af60-4641fcf98b6b' User entered '30 Jan 2021 06:37:32'	System	30 Jan 2021 12:37:36
	System	30 Jan 2021 12:37:36

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '30 Jan 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '03 Feb 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 173'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-06T06:52:47', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f272db5b-a9ef-4be9-a7bf-1e38e803c1cc' User entered 'No (N)'	System	06 Feb 2021 12:52:57

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-06T06:52:50', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f272db5b-a9ef-4be9-a7bf-1e38e803c1cc' User entered 'No (N)'	System	06 Feb 2021 12:52:57

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-06T06:52:54', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f272db5b-a9ef-4be9-a7bf-1e38e803c1cc' User entered '06 Feb 2021 06:52:54'	System	06 Feb 2021 12:52:57

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '06 Feb 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '10 Feb 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 180'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-13T00:02:10', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '612525b7-b0d2-4924-b7aa-2ff1b5431621' User entered 'No (N)'	System	13 Feb 2021 06:02:27
	System	13 Feb 2021 06:02:27

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-13T00:02:16', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '612525b7-b0d2-4924-b7aa-2ff1b5431621' User entered 'No (N)'	System	13 Feb 2021 06:02:27
	System	13 Feb 2021 06:02:27

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-13T00:02:19', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '612525b7-b0d2-4924-b7aa-2ff1b5431621' User entered '13 Feb 2021 00:02:19'	System	13 Feb 2021 06:02:27
	System	13 Feb 2021 06:02:27

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '13 Feb 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '17 Feb 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 187'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-20T01:11:23', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '21909bf2-c97c-47a1-b3e5-fd89bd6ab87a' User entered 'Yes (Y)'	System	20 Feb 2021 07:12:11
	System	20 Feb 2021 07:12:11

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-20T01:11:31', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '21909bf2-c97c-47a1-b3e5-fd89bd6ab87a' User entered 'No (N)'	System	20 Feb 2021 07:12:11

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-20T01:11:36', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '21909bf2-c97c-47a1-b3e5-fd89bd6ab87a' User entered 'No (N)'	System	20 Feb 2021 07:12:11
	System	20 Feb 2021 07:12:11

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-20T01:11:47', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '21909bf2-c97c-47a1-b3e5-fd89bd6ab87a' User entered 'Yes (Y)'	System	20 Feb 2021 07:12:11
	System	20 Feb 2021 07:12:11

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-20T01:11:57', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '21909bf2-c97c-47a1-b3e5-fd89bd6ab87a'	System	20 Feb 2021 07:12:11
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	20 Feb 2021 07:12:11

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-20T01:12:00', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '21909bf2-c97c-47a1-b3e5-fd89bd6ab87a' User entered '20 Feb 2021 01:12:00'	System	20 Feb 2021 07:12:11
	System	20 Feb 2021 07:12:11

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '20 Feb 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '24 Feb 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 194'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-27T00:01:43', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6ee9bd7d-2374-4998-a715-c9c68fdac6fc' User entered 'No (N)'	System	27 Feb 2021 06:02:26
	System	27 Feb 2021 06:02:26

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-27T00:01:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6ee9bd7d-2374-4998-a715-c9c68fdac6fc' User entered 'No (N)'	System	27 Feb 2021 06:02:26

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-27T00:01:52', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6ee9bd7d-2374-4998-a715-c9c68fdac6fc' User entered '27 Feb 2021 00:01:52'	System	27 Feb 2021 06:02:26
	System	27 Feb 2021 06:02:26

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '27 Feb 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '03 Mar 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 201'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-06T00:01:28', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '01dfbc19-98d2-4656-afed-1b2a36f63286'	System	06 Mar 2021 06:10:13
User entered 'No (N)'	System	06 Mar 2021 06:10:13

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-06T00:01:31', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '01dfbc19-98d2-4656-afed-1b2a36f63286'	System	06 Mar 2021 06:10:13
User entered 'No (N)'	System	06 Mar 2021 06:10:13

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-06T00:01:36', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '01dfbc19-98d2-4656-afed-1b2a36f63286' User entered '06 Mar 2021 00:01:36'	System	06 Mar 2021 06:10:13
	System	06 Mar 2021 06:10:13

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '06 Mar 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '10 Mar 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 208'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-13T04:32:30', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6286ef89-fe93-431f-a31a-45e039580c68' User entered 'No (N)'	System	13 Mar 2021 10:32:42

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-13T04:32:33', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6286ef89-fe93-431f-a31a-45e039580c68' User entered 'No (N)'	System	13 Mar 2021 10:32:42

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-13T04:32:38', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '6286ef89-fe93-431f-a31a-45e039580c68' User entered '13 Mar 2021 04:32:38'	System	13 Mar 2021 10:32:42
	System	13 Mar 2021 10:32:42

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '13 Mar 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '17 Mar 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 215'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-20T00:58:52', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f9e00261-67c2-4e59-9551-87044fed85f3' User entered 'No (N)'	System	20 Mar 2021 05:59:06
	System	20 Mar 2021 05:59:06

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-20T00:58:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f9e00261-67c2-4e59-9551-87044fed85f3'	System	20 Mar 2021 05:59:06
User entered 'No (N)'	System	20 Mar 2021 05:59:06

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-20T00:58:59', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'f9e00261-67c2-4e59-9551-87044fed85f3' User entered '20 Mar 2021 00:58:59'	System	20 Mar 2021 05:59:06
	System	20 Mar 2021 05:59:06

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '20 Mar 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '24 Mar 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 222'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-27T00:01:42', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0592e910-ca70-4742-9059-090a77284507' User entered 'No (N)'	System	27 Mar 2021 05:01:54

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-27T00:01:45', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0592e910-ca70-4742-9059-090a77284507' User entered 'No (N)'	System	27 Mar 2021 05:01:54

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-03-27T00:01:49', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '0592e910-ca70-4742-9059-090a77284507' User entered '27 Mar 2021 00:01:49'	System	27 Mar 2021 05:01:54

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '27 Mar 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '31 Mar 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 229'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-03T07:11:18', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '650cb7aa-cc51-4988-9e50-4f7b0ace4896' User entered 'No (N)'	System	03 Apr 2021 12:11:29
	System	03 Apr 2021 12:11:29

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-03T07:11:20', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '650cb7aa-cc51-4988-9e50-4f7b0ace4896' User entered 'No (N)'	System	03 Apr 2021 12:11:29

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-03T07:11:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '650cb7aa-cc51-4988-9e50-4f7b0ace4896'	System	03 Apr 2021 12:11:29
User entered '03 Apr 2021 07:11:25'	System	03 Apr 2021 12:11:29

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '03 Apr 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '07 Apr 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 236'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-10T03:01:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '8da83124-2534-4c98-bd85-89aeb540f622' User entered 'No (N)'	System	10 Apr 2021 08:01:43
	System	10 Apr 2021 08:01:43

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-10T03:01:32', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '8da83124-2534-4c98-bd85-89aeb540f622'	System	10 Apr 2021 08:01:43
User entered 'No (N)'	System	10 Apr 2021 08:01:43

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-10T03:01:39', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '8da83124-2534-4c98-bd85-89aeb540f622' User entered '10 Apr 2021 03:01:39'	System	10 Apr 2021 08:01:43
	System	10 Apr 2021 08:01:43

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '10 Apr 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '14 Apr 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 243'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-17T00:01:46', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd195209-a65e-4529-99d2-fed5129770fd' User entered 'No (N)'	System	17 Apr 2021 05:02:12
	System	17 Apr 2021 05:02:12

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-17T00:01:55', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd195209-a65e-4529-99d2-fed5129770fd' User entered 'No (N)'	System	17 Apr 2021 05:02:12

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-17T00:02:07', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: 'fd195209-a65e-4529-99d2-fed5129770fd' User entered '17 Apr 2021 00:02:07'	System	17 Apr 2021 05:02:12
	System	17 Apr 2021 05:02:12

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '17 Apr 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '21 Apr 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 250'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-24T00:24:03', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '9c137bb9-f777-496a-aa56-5c60db00f57e' User entered 'No (N)'	System	24 Apr 2021 05:24:13
	System	24 Apr 2021 05:24:13

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-24T00:24:06', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '9c137bb9-f777-496a-aa56-5c60db00f57e' User entered 'No (N)'	System	24 Apr 2021 05:24:13

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-04-24T00:24:09', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '9c137bb9-f777-496a-aa56-5c60db00f57e' User entered '24 Apr 2021 00:24:09'	System	24 Apr 2021 05:24:13
	System	24 Apr 2021 05:24:13

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '24 Apr 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '28 Apr 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 257'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-05-01T00:09:22', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '52803b87-6f41-4f57-bfa7-66b3cd170d98'	System	01 May 2021 05:21:54
User entered 'No (N)'	System	01 May 2021 05:21:54

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-05-01T00:09:25', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '52803b87-6f41-4f57-bfa7-66b3cd170d98'	System	01 May 2021 05:21:54
User entered 'No (N)'	System	01 May 2021 05:21:54

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-05-01T00:09:31', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '52803b87-6f41-4f57-bfa7-66b3cd170d98'	System	01 May 2021 05:21:54
User entered '01 May 2021 00:09:31'	System	01 May 2021 05:21:54

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '01 May 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '05 May 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 264'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '08 May 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '12 May 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 271'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '15 May 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '19 May 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 278'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '22 May 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '26 May 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 285'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '29 May 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '02 Jun 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 292'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '05 Jun 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '09 Jun 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 299'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '12 Jun 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '16 Jun 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 306'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '19 Jun 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '23 Jun 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 313'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '26 Jun 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '30 Jun 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 320'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '03 Jul 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '07 Jul 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 327'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '10 Jul 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '14 Jul 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 334'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '17 Jul 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '21 Jul 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 341'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '24 Jul 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '28 Jul 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 348'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '31 Jul 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '04 Aug 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 355'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '07 Aug 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '11 Aug 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 362'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '14 Aug 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '18 Aug 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 369'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '21 Aug 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '25 Aug 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 376'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '28 Aug 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '01 Sep 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 383'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '04 Sep 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '08 Sep 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 390'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '11 Sep 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '15 Sep 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 397'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '18 Sep 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '22 Sep 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 404'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '25 Sep 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '29 Sep 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 411'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '02 Oct 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '06 Oct 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 418'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '09 Oct 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '13 Oct 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 425'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '16 Oct 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '20 Oct 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 432'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '23 Oct 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '27 Oct 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 439'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '30 Oct 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '03 Nov 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 446'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '06 Nov 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '10 Nov 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 453'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '13 Nov 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '17 Nov 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 460'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '20 Nov 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '24 Nov 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 467'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '27 Nov 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '01 Dec 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 474'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '04 Dec 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '08 Dec 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 481'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '11 Dec 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '15 Dec 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 488'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '18 Dec 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '22 Dec 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 495'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '25 Dec 2021 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '29 Dec 2021 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 502'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '01 Jan 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '05 Jan 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 509'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '08 Jan 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '12 Jan 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 516'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '15 Jan 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '19 Jan 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 523'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '22 Jan 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '26 Jan 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 530'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '29 Jan 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '02 Feb 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 537'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '05 Feb 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '09 Feb 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 544'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '12 Feb 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '16 Feb 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 551'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '19 Feb 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '23 Feb 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 558'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '26 Feb 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '02 Mar 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 565'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '05 Mar 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '09 Mar 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 572'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '12 Mar 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '16 Mar 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 579'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '19 Mar 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '23 Mar 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 586'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '26 Mar 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '30 Mar 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 593'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '02 Apr 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '06 Apr 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 600'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '09 Apr 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '13 Apr 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 607'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '16 Apr 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '20 Apr 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 614'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '23 Apr 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '27 Apr 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 621'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '30 Apr 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '04 May 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 628'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '07 May 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '11 May 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 635'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '14 May 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '18 May 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 642'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '21 May 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '25 May 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 649'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '28 May 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '01 Jun 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 656'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '04 Jun 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '08 Jun 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 663'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '11 Jun 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '15 Jun 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 670'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '18 Jun 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '22 Jun 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 677'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '25 Jun 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '29 Jun 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 684'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '02 Jul 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '06 Jul 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 691'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '09 Jul 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '13 Jul 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 698'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '16 Jul 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '20 Jul 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 705'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '23 Jul 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '27 Jul 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 712'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '30 Jul 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '03 Aug 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 719'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '06 Aug 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '10 Aug 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 726'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '13 Aug 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '17 Aug 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 733'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '20 Aug 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '24 Aug 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 740'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '27 Aug 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '31 Aug 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 747'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '03 Sep 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '07 Sep 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 754'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '10 Sep 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '14 Sep 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 761'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '17 Sep 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '21 Sep 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 768'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '24 Sep 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '28 Sep 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 775'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '01 Oct 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '05 Oct 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 782'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '08 Oct 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '12 Oct 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 789'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '15 Oct 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '19 Oct 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered 'Day 796'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '22 Oct 2022 00:01'	System	20 Nov 2020 00:11:25

US3292259

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	20 Nov 2020 00:11:25
Amendment Manager: User entered '26 Oct 2022 23:59'	System	20 Nov 2020 00:11:25

US3292259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:28:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:01:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-28T23:13:23', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '73124550-ad25-4906-a089-a76e5a1f7177'	System	01 Mar 2021 05:13:33
User entered 'No (N)'	System	01 Mar 2021 05:13:33

US3292259

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:28:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:01:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (95B99546-B4FC-4A50-98B3-1A0810635DD9)', Time: '2021-02-28T23:13:29', User OID: 'PatientReportedOutcome (US3292259)', ODM File OID: '73124550-ad25-4906-a089-a76e5a1f7177' User entered '28 Feb 2021 23:13:29'	System	01 Mar 2021 05:13:33
	System	01 Mar 2021 05:13:33

US3292259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	24 Nov 2020 21:15:40

US3292259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '13 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	24 Nov 2020 21:15:40

US3292259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	24 Nov 2020 21:15:40

US3292259

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	24 Nov 2020 21:15:40

US3292259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	24 Nov 2020 21:15:44

US3292259

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:23:35
User entered 'l'	System	24 Nov 2020 21:15:44

US3292259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 17:44:31

US3292259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '19 Dec 2020'	(b) (4), (b) (6)	22 Dec 2020 17:44:31

US3292259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	22 Dec 2020 17:44:31

US3292259

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 17:44:31

US3292259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	22 Dec 2020 17:54:05

US3292259

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User entered 'l'	System	22 Dec 2020 17:54:05

US3292259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:30:59

US3292259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '15 Jan 2021'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:30:59

US3292259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:30:59

US3292259

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:30:59

US3292259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:31:02

US3292259

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User entered 'l'	System	18 Jan 2021 20:31:02

US3292259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 15:43:27

US3292259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16 Feb 2021'	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 15:43:27

US3292259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 15:43:27

US3292259

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 15:43:27

US3292259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 15:43:33

US3292259

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:35:29
User entered 'l'	System	17 Feb 2021 15:43:33

US3292259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:06:57

US3292259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User closed query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 15:33:51
Query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'OOW noted in PD log' (Site from System).	Nathan Cortez (b) (4)	08 Apr 2021 17:07:06
User opened query 'Visit 4 Date is < 166 days or > 194 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	08 Apr 2021 17:06:57
User entered '7 Apr 2021'	Nathan Cortez (b) (4)	08 Apr 2021 17:06:57

US3292259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Clinic (Clinic)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:06:57

US3292259

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	08 Apr 2021 17:06:57

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '7 Apr 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '13:14'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Apr 2021 13:14'	System	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '36.8' C	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Oral (Oral)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '89'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '16'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '141'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '87'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 17:09:17

US3292259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:28

US3292259

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '7 Apr 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:28

US3292259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:49

US3292259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '7 Apr 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:49

US3292259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '13:34'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:49

US3292259

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Apr 2021 13:34'	System	08 Apr 2021 17:09:49

US3292259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:09:56

US3292259

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 17:09:56

US3292259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:06:53

US3292259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '15 Apr 2021'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:06:53

US3292259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:06:53

US3292259

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:06:53

US3292259

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Apr 2021 15:06:56

US3292259

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	16 Apr 2021 15:06:56

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '13 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:49:34

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '13:23'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:49:34

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:30
User entered '13 Nov 2020 13:23'	System	18 Nov 2020 18:49:34

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Safety Call (Safety Call)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:49:34

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:49:34

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 1 (Day 1)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:18:18
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '07 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
Signature has been broken.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:18:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
Signature has been broken.	(b) (4), (b) (6)	20 Apr 2021 15:18:28
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per CDM: It appears that multiple values for Day1 - Day 9 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 09:55:59
Query 'Per CDM: It appears that multiple values for Day1 - Day 9 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'COMPLETED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:24:25
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:14:50
User opened query 'Per CDM: It appears that multiple values for Day1 - Day 9 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:28:08
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:01:04
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:01:04
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:01:04
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:01:04
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:01:04
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:01:04
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:50:43

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 2 (Day 2)' reason for change:	(b) (4)	
Data Entry Error	Nathan Cortez (b) (4)	18 Nov 2020 19:02:43
User entered empty.	(b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
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	18 Nov 2020 19:02:43
User entered '08 Nov 2020' reason for change: Data Entry Error	System	18 Nov 2020 19:02:43
User opened query 'Data is required. Please complete.' (Site from System).	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07
User entered empty.	System	18 Nov 2020 18:58:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:02:43
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:02:43
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:02:43
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)' reason for change: Data Entry Error	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 19:02:43
User entered empty.	(b) (4)	
	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07
	(b) (4)	

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 18:58:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 3 (Day 3)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '09 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:03:17

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 4 (Day 4)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '10 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	(b) (4), (b) (6)
User entered empty.	Nathan Cortez (b) (4)	25 Jan 2021 19:14:50
		18 Nov 2020 19:04:07

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:04:07

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 5 (Day 5)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '11 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:05:36

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 6 (Day 6)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '12 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	(b) (4), (b) (6)
User entered empty.	Nathan Cortez (b) (4)	25 Jan 2021 19:14:50
		18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:06:30

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 7 (Day 7)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '13 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:07:05

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 8 (Day 8)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '14 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:12:01

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 9 (Day 9)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '15 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	25 Jan 2021 19:14:50
User entered empty.	System	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	25 Jan 2021 19:14:50
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:19:40
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:22:32
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:23:55
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:13:19

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 10 (Day 10)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '94'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '37.3' C	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:16:20

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
Signature has been broken.	(b) (4)	
	(b) (4), (b) (6)	20 Apr 2021 15:17:08
User entered 'Day 13 (Day 13)' reason for change:		20 Apr 2021 15:17:08
Data Entry Error		
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
	(b) (4)	
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:42:41
User entered 'Day 2 (Day 2)' reason for change:		14 Apr 2021 01:42:41
Data Entry Error		
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered 'Day 11 (Day 11)'	Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User closed query 'Per CDM RQ: Previous response noted,however Symptom day has been updated to Day 2 which already exists on the date of 08 Nov 2020.Please reconcile and update the date as appropriate.' (Site from DM).		21 Apr 2021 16:05:06
Query 'Per CDM RQ: Previous response noted,however Symptom day has been updated to Day 2 which already exists on the date of 08 Nov 2020.Please reconcile and update the date as appropriate.' answered with 'Updated' (Site from DM).		20 Apr 2021 15:17:24
User opened query 'Per CDM RQ: Previous response noted,however Symptom day has been updated to Day 2 which already exists on the date of 08 Nov 2020.Please reconcile and update the date as appropriate.' (Site from DM).		16 Apr 2021 16:52:25
User closed query 'per CDM: this date is also listed for symptom day 14, please clarify day 11 date' (Site from DM).		16 Apr 2021 16:52:25
Query 'per CDM: this date is also listed for symptom day 14, please clarify day 11 date' answered with 'Updated ' (Site from DM).		14 Apr 2021 01:42:53
User opened query 'per CDM: this date is also listed for symptom day 14, please clarify day 11 date' (Site from DM).	Doug Dunford (b) (4) (b) (4)	15 Mar 2021 23:33:08
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:29:54
User entered '17 Nov 2020'	Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '100'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.0' C	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (11)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:17:54

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
Signature has been broken.	(b) (4)	20 Apr 2021 15:17:08
User entered 'Day 14 (Day 14)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:17:08
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
Signature has been broken.	(b) (4)	14 Apr 2021 01:43:51
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 01:43:51
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 12 (Day 12)'	(b) (4)	20 Nov 2020 20:06:23
	Gerardo Pena (b) (4)	
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

Date

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User closed query 'Per CDM RQ: Previous response noted,however Symptom day has been updated to Day 3 which already exists on the date of 09 Nov 2020.Please reconcile and update the date as appropriate.' (Site from DM).		21 Apr 2021 16:05:20
Query 'Per CDM RQ: Previous response noted,however Symptom day has been updated to Day 3 which already exists on the date of 09 Nov 2020.Please reconcile and update the date as appropriate.' answered with 'Updated' (Site from DM).		20 Apr 2021 15:17:42
User opened query 'Per CDM RQ: Previous response noted,however Symptom day has been updated to Day 3 which already exists on the date of 09 Nov 2020.Please reconcile and update the date as appropriate.' (Site from DM).		16 Apr 2021 16:53:33
User closed query 'per CDM: this date listed for day 15, please clarify day 12's date' (Site from DM).		16 Apr 2021 16:53:33
Query 'per CDM: this date listed for day 15, please clarify day 12's date' answered with 'Updated ' (Site from DM).		14 Apr 2021 01:44:06
User opened query 'per CDM: this date listed for day 15, please clarify day 12's date' (Site from DM).	Doug Dunford (b) (4)	15 Mar 2021 23:33:45
User signature succeeded.	(b) (4)	
	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '18 Nov 2020'	Gerardo Pena (b) (4)	20 Nov 2020 20:06:23
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '100'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	20 Nov 2020 20:06:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.0' C	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (12)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 20:06:23

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
Signature has been broken.	(b) (4)	20 Apr 2021 15:17:08
User entered 'Day 15 (Day 15)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 15:17:08
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 13 (Day 13)'	(b) (4)	
	Gerardo Pena (b) (4)	23 Nov 2020 16:31:48
	(b) (4)	

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Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User closed query 'Per CDM RQ: Previous response noted,however date has not been updated. Please review and update as appropriate.' (Site from DM).		21 Apr 2021 16:05:32
Query 'Per CDM RQ: Previous response noted,however date has not been updated. Please review and update as appropriate.' answered with 'Updated' (Site from DM).		20 Apr 2021 15:17:58
User opened query 'Per CDM RQ: Previous response noted,however date has not been updated. Please review and update as appropriate.' (Site from DM).		16 Apr 2021 16:55:13
User closed query 'per CDM: this date also listed for day 16, please clarify day 13's date' (Site from DM).		16 Apr 2021 16:55:13
Query 'per CDM: this date also listed for day 16, please clarify day 13's date' answered with 'Updated ' (Site from DM).		14 Apr 2021 01:44:44
User opened query 'per CDM: this date also listed for day 16, please clarify day 13's date' (Site from DM).	Doug Dunford (b) (4)	15 Mar 2021 23:34:19
User signature succeeded.	(b) (4)	
	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '19 Nov 2020'	Gerardo Pena (b) (4)	23 Nov 2020 16:31:48
	(b) (4)	

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Form: Symptom Log (13)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

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[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '100'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User entered '%'	System	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.2' C	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Symptom Log (13)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:40
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 16:31:48

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

Did Subject Test Positive For SARS-CoV-2 by RT-PCR?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per CDM: Thanks for the response, please update the field as soon as the data is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 12:05:11
Query 'Per CDM: Thanks for the response, please update the field as soon as the data is available. Thank you.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	28 Dec 2020 16:14:44
User entered 'No (N)' reason for change: Per Query Resolution	Gerardo Pena (b) (4)	28 Dec 2020 16:14:38
User opened query 'Per CDM: Thanks for the response, please update the field as soon as the data is available. Thank you.' (Site from DM).	(b) (4), (b) (6)	04 Dec 2020 05:53:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	04 Dec 2020 05:53:09
Query 'Data is required. Please complete.' answered with 'Pending results' (Site from System).	Nathan Cortez (b) (4)	18 Nov 2020 19:21:57
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Nov 2020 19:21:42
User entered empty.	Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:21:42

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:47
User entered '0'	System	28 Dec 2020 16:14:38

US3292259

Folder: Covid-19 Assessment 13 Nov 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:28:39

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 17:22:53
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	28 Dec 2020 16:20:39
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	28 Dec 2020 16:20:33
User entered 'Yes (Y)'	(b) (4)	
	Gerardo Pena (b) (4)	28 Dec 2020 15:47:58
	(b) (4)	

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Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:20:51
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per GCL Lab Reconciliation, Per GCL there is a Swab sample with a Collection Date of 22DEC2020, however, this sample is not recorded in the CRF. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:05:09
Query 'Per GCL Lab Reconciliation, Per GCL there is a Swab sample with a Collection Date of 22DEC2020, however, this sample is not recorded in the CRF. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	21 Feb 2021 18:14:39
User opened query 'Per GCL Lab Reconciliation, Per GCL there is a Swab sample with a Collection Date of 22DEC2020, however, this sample is not recorded in the CRF. Please complete the COVID Diagnostic Test form within this folder, as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 22:20:29
User entered '21 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:26:39

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:20:51
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '09:58'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:26:39

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:20:51
User entered '21 Dec 2020 09:58'	System	29 Dec 2020 16:26:39

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:20:51
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Safety Call (Safety Call)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:26:39

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:39

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:20:51
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:26:39

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 1 (Day 1)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '19 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User entered empty.	System	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:40:29

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 2 (Day 2)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User entered empty.	System	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:41:16

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 3 (Day 3)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '98'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User entered '%'	System	29 Dec 2020 16:44:11

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.9' C	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Severe (Severe)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Severe (Severe)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Severe (Severe)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Moderate (Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:44:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 4 (Day 4)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '23 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '97'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User entered '%'	System	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.5' C	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4)	29 Dec 2020 16:45:11

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 5 (Day 5)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '24 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '99'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User entered '%'	System	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:47:42

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:47:42

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 6 (Day 6)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '25 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '100'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User entered '%'	System	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.7' C	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:49:36

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:49:36

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 7 (Day 7)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '26 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '100'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User entered '%'	System	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:50:34

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Day 8 (Day 8)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '27 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '0'	(b) (4), (b) (6)	29 Dec 2020 17:53:06

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '100'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User entered '%'	System	29 Dec 2020 17:53:06

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.5' C	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

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Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:28:39

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:03
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	29 Dec 2020 17:53:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

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Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:35:06

US3292259

Folder: Covid-19 Assessment 21 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:28:39

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:21:10
User entered '0'	System	18 Jan 2021 20:35:06

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User accepted default value 'Day 3 (Day 3)'	Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:15:27

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 16:15:27

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '18 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 16:15:27

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User accepted default value 'Day 5 (Day 5)'	Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:16:30

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 16:16:30

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '20 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 16:16:30

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User accepted default value 'Day 7 (Day 7)'		17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User accepted default value 'Day 9 (Day 9)'		17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User accepted default value 'Day 14 (Day 14)'		17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User accepted default value 'Day 21 (Day 21)'		17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User accepted default value 'Day 28 (Day 28)'		17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'NA (COVID-19 Negative) (NA)'	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	17 Feb 2021 21:57:22

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 3 (Day 3)'	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '24 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 5 (Day 5)'	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '26 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 7 (Day 7)'	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 21:35:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:35:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:35:11
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 20:36:51
User entered empty.	Gerardo Pena (b) (4)	18 Jan 2021 20:36:51
	(b) (4)	

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:35:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:35:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:35:11
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 20:36:51
User entered empty.	Gerardo Pena (b) (4)	18 Jan 2021 20:36:51
	(b) (4)	

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 21:35:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:35:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:35:11
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 20:36:51
User entered empty.	Gerardo Pena (b) (4)	18 Jan 2021 20:36:51
	(b) (4)	

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 21:35:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:35:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:35:11
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 20:36:51
User entered empty.	Gerardo Pena (b) (4)	18 Jan 2021 20:36:51
	(b) (4)	

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:28:39

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:28:39

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 21:35:11
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:35:11
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:35:11
User opened query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 20:36:51
User entered empty.	Gerardo Pena (b) (4)	18 Jan 2021 20:36:51
	(b) (4)	

US3292259

Folder: Illness Visit (2)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:36:51

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 and 20NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:41:52
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 and 20NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' answered with 'log updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 21:58:58
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 18NOV2020 and 20NOV2020 are reported under Illness visit in PPD Central lab, however the data is missing in EDC. Please review if the sample has been collected for illness visit and update the details in Saliva collection log under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 05:01:09
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	18 Nov 2020 19:23:43

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:23:43

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Home (Home)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:23:43

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:02
User entered 'SICKD1'	System	18 Nov 2020 19:23:43

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '17:22'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User entered '16 Nov 2020 17:22'	System	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '162.6' cm	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24
DataPoint set to visible.	System	18 Nov 2020 19:23:43

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '77.1' kg	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24
DataPoint set to visible.	System	18 Nov 2020 19:23:43

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '37.3' C	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Oral (Oral)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '89'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User entered 'bpm'	System	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '17'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User entered 'breaths/min'	System	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '129'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User entered 'mmHg'	System	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '85'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06
User entered 'mmHg'	System	18 Nov 2020 19:24:24

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:06

US3292259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:41

US3292259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:24:41

US3292259

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:28:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:25:17

US3292259

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:43:13
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	18 Nov 2020 19:25:17

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24DEC2020 and 26DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:43:17
Query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24DEC2020 and 26DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' answered with 'log updated' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 22:02:28
User opened query 'Per GCL LAB reconciliation: Saliva: PPD Central lab reports sample dated 24DEC2020 and 26DEC2020 labelled as Illness Visit which is missing in EDC. Please confirm if the sample has been collected then record on the Saliva collection form. Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Jan 2021 02:40:09
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	28 Dec 2020 16:22:20

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:22:20

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Home (Home)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:22:20

US3292259

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'SICKD1'	System	28 Dec 2020 16:22:20

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '12:30'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '22 Dec 2020 12:30'	System	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Height \(xxx.x\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '160.02' cm	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 16:25:30
DataPoint set to visible.	(b) (4) System	28 Dec 2020 16:22:20

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Weight (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '77.11' kg	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 16:25:30
DataPoint set to visible.	(b) (4) System	28 Dec 2020 16:22:20

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.9' C	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '81'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '17'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '128'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '78'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	28 Dec 2020 16:25:30

US3292259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:26:31

US3292259

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:26:31

US3292259

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:28:39

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:26:06

US3292259

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:28:39

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Dec 2020 16:26:06

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:38:26

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:38:26

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Clinic (Clinic)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:38:26

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'UNBLND_DECIDE'	System	28 Jan 2021 20:38:26

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:06:50

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4) System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:06:50

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Placebo (Placebo)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Placebo (Placebo)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Placebo (Placebo)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'I'	System	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 16:28:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'I'	System	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	28 Jan 2021 20:41:25
DataPoint set to visible.	System	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	28 Jan 2021 20:41:25
DataPoint set to visible.	System	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User accepted default value 'Pre-Dose (PREDOSE)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '09:21'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '28 Jan 2021 09:21'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.4' C	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Oral (Oral)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '79'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'bpm'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'breaths/min'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '131'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'mmHg'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '89'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'mmHg'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered missing code ND - Not Done.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	28 Jan 2021 20:41:25
DataPoint set to visible.	System	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User accepted default value 'Post-Dose (POSTDOSE)'	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '10:40'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '28 Jan 2021 10:40'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '36.7' C	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Oral (Oral)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '85'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'bpm'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '16'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'breaths/min'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '138'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'mmHg'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '89'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'mmHg'	System	28 Jan 2021 20:41:25

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:09

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4) (b) (4)	28 Jan 2021 20:40:09

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

Date of test (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Jan 2021 20:40:32
User entered 'Urine (URINE)' reason for change: Data Entry Error	Dawn Killian (b) (4)	28 Jan 2021 20:40:32
User opened query 'Data is required. Please provide.' (Site from System).	(b) (4) System	28 Jan 2021 20:40:28
User entered empty.	Dawn Killian (b) (4)	28 Jan 2021 20:40:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Negative (NEGATIVE)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was FSH sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered empty.	System	28 Jan 2021 20:40:28

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'mRNA-1273'	System	28 Jan 2021 20:40:19
DataPoint set to visible.	System	28 Jan 2021 20:39:23

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '10:10'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '28 Jan 2021 10:10'	System	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Left Arm (LEFT ARM)'	(b) (4) Dawn Killian (b) (4) (b) (4)	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'ONCE'	System	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'INTRAMUSCULAR'	System	28 Jan 2021 20:40:19

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:38:59

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:38:59

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '09:28'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:38:59

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '28 Jan 2021 09:28'	System	28 Jan 2021 20:38:59

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:07

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '28 Jan 2021'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:07

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '09:40'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:39:07

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:39

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered '28 Jan 2021 09:40'	System	28 Jan 2021 20:39:07

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	28 Jan 2021 20:40:01

US3292259

Folder: Participant Decision Visit / OL-D1 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 20:17:50
User entered 'I'	System	28 Jan 2021 20:40:01

US3292259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 18:09:28

US3292259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '4 Feb 2021'	(b) (4), (b) (6)	05 Feb 2021 18:09:28

US3292259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	05 Feb 2021 18:09:28

US3292259

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered empty.	(b) (4), (b) (6)	05 Feb 2021 18:09:28

US3292259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	05 Feb 2021 18:09:34

US3292259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User entered 'l'	System	05 Feb 2021 18:09:34

US3292259

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 07:37:23
User entered 'I'	System	05 Feb 2021 18:09:34
DataPoint set to visible.	System	05 Feb 2021 18:09:34

US3292259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:46:13

US3292259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '11 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:46:13

US3292259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[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 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:46:13

US3292259

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered 'OLD29'	System	12 Mar 2021 21:46:13

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '11 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '09:15'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered '11 Mar 2021 09:15'	System	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '36.7' C	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '70'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered 'bpm'	System	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '16'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered 'breaths/min'	System	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '123'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered 'mmHg'	System	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '84'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered 'mmHg'	System	12 Mar 2021 21:47:08

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:47:26

US3292259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:37

US3292259

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '11 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:47:37

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Was the pregnancy test performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:48:02

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

Date of test (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '11 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:48:02

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Test performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Urine (URINE)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:48:02

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Result](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Negative (NEGATIVE)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:48:02

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

Was FSH sample collected?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
Query 'Per CDM: Please verify Was pregnancy test performed? is recorded as Yes; However Was FSH sample collected? Is recorded as "NO". Please review and update accordingly, Else clarify.' canceled (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:32:34
User opened query 'Per CDM: Please verify Was pregnancy test performed? is recorded as Yes; However Was FSH sample collected? Is recorded as "NO". Please review and update accordingly, Else clarify.' (Site from DM).		19 Mar 2021 16:14:08
User entered 'No (N)'	Gerardo Pena (b) (4)	12 Mar 2021 21:48:02

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:48:02

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:48:02

US3292259

Folder: OL-D29 (1)

Form: Pregnancy Test

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:48:02

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Participant declined due to Adverse Event (ADVERSE EVENT)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:52:55
DataPoint set to visible.	System	05 Feb 2021 18:09:34

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered empty.	System	12 Mar 2021 21:52:55

US3292259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Mar 2021 21:53:01

US3292259

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:18:39
User entered 'l'	System	12 Mar 2021 21:53:01

US3292259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	19 Mar 2021 14:56:14

US3292259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '18 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	19 Mar 2021 14:56:14

US3292259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	19 Mar 2021 14:56:14

US3292259

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Mar 2021 14:56:14

US3292259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	19 Mar 2021 14:56:19

US3292259

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 05:36:25
User entered 'l'	System	19 Mar 2021 14:56:19

US3292259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:10

US3292259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '7 Apr 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:10

US3292259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Clinic (Clinic)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:10

US3292259

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:39

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	08 Apr 2021 17:10:10

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '7 Apr 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '13:14'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Apr 2021 13:14'	System	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '36.8' C	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Oral (Oral)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '89'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Pulse units](#)

Audit	User	Time (GMT)
User entered 'bpm'	System	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '16'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered 'breaths/min'	System	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '141'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '87'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered 'mmHg'	System	08 Apr 2021 17:10:45

US3292259

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:57

US3292259

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '7 Apr 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:10:57

US3292259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:11:10

US3292259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '7 Apr 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:11:10

US3292259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '13:34'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:11:10

US3292259

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:39

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '7 Apr 2021 13:34'	System	08 Apr 2021 17:11:10

US3292259

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:28:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:25
DataPoint Verified.		05 Apr 2021 20:40:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	02 Sep 2020 21:12:03

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per CDM: Please update event to specify which eye (Right, Left, or bilateral) and ensure to reconcile with the CM page so there is a match as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Dec 2020 06:28:34
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Eye infection, LLT: Eye infection - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 16:59:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Dec 2020 16:59:31
Data point term sent to Coder	System	22 Dec 2020 16:57:46
Query 'Per CDM: Please update event to specify which eye (Right, Left, or bilateral) and ensure to reconcile with the CM page so there is a match as appropriate. ' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 16:57:41
Coding entries removed.		22 Dec 2020 16:57:27
User entered 'left EYE INFECTION' reason for change: Data Entry Error		22 Dec 2020 16:57:27
User opened query 'Per CDM: Please update event to specify which eye (Right, Left, or bilateral) and ensure to reconcile with the CM page so there is a match as appropriate. ' (Site from DM).		13 Nov 2020 22:32:58
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Eye and eyelid infections, PT: Eye infection, LLT: Eye infection - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 21:23:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Sep 2020 21:23:47
Data point term sent to Coder	System	23 Sep 2020 21:22:39
User entered 'Eye Infection'	Dawn Killian (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '30 Aug 2020'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Dawn Killian (b) (4)	04 Nov 2020 18:36:32
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
	(b) (4)	
User entered '17 Sep 2020' reason for change: Data Entry Error	Dawn Killian (b) (4)	04 Nov 2020 18:36:32
	(b) (4)	
User entered empty.	Dawn Killian (b) (4)	23 Sep 2020 21:22:14
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

US3292259

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) Dawn Killian (b) (4)	04 Nov 2020 18:36:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Dawn Killian (b) (4)	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Sep 2020 21:22:14

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with body aches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of Covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:12:17
Query 'Per MM, this subject presented with body aches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of Covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'this subject entered convalescent period, nasal swab negative for COVID-19' (Site from DM).		18 Feb 2021 02:19:08
User opened query 'Per MM, this subject presented with body aches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of Covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		16 Feb 2021 14:07:14
User closed query 'Per MM, this subject presented with bodyaches, muscleaches, chills, fatigue, nausea, headaches (onsets 07Nov2020), fever, cough, shortness of breath, difficulty breathing, sorethroat, diarrhea, nasal congestion and diarrhea (onsets 16Nov2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		19 Jan 2021 13:41:09
User closed query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES. If yes, note that this AE overlaps with AE #4. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification. ' (Site from DM).		19 Jan 2021 12:25:26

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per MM, this subject presented with bodyaches, muscleaches, chills, fatigue, nausea, headaches (onsets 07Nov2020), fever, cough, shortness of breath, difficulty breathing, sorethroat, diarrhea, nasal congestion and diarrhea (onsets 16Nov2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'Subject has tested negative for COVID-19 twice as of 22DEC2020.' (Site from DM).	Gerardo Pena (b) (4)	18 Jan 2021 20:39:39
Query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES. If yes, note that this AE overlaps with AE #4. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.'	Gerardo Pena (b) (4)	18 Jan 2021 20:38:46
' answered with 'No overlap; body aches and muscle aches are separate when assessing symptoms.' (Site from DM).		
User opened query 'Per MM, this subject presented with bodyaches, muscleaches, chills, fatigue, nausea, headaches (onsets 07Nov2020), fever, cough, shortness of breath, difficulty breathing, sorethroat, diarrhea, nasal congestion and diarrhea (onsets 16Nov2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 19:42:01
User opened query 'Per DM CLR: Please verify if this pertains to MUSCLE ACHES. If yes, note that this AE overlaps with AE #4. Please reconcile and update AE entries so there is no overlap or duplicate data. Otherwise, provide clarification.'		08 Dec 2020 06:06:10
' (Site from DM).		
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Pain, LLT: General body pain - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 18:53:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 18:53:02
Data point term sent to Coder	System	19 Nov 2020 18:52:27
User entered 'body aches'	Gerardo Pena (b) (4)	19 Nov 2020 18:51:33

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EAB) (1725)

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

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Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '7 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 12:25:54
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'AE is resolved.' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:40:01
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:33:43
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:57:14
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
	(b) (4)	
User entered '24 Dec 2020' reason for change: New Information	Gerardo Pena (b) (4)	18 Jan 2021 20:33:43
	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	19 Nov 2020 18:51:33
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:51:33
	(b) (4)	

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:51:33
	(b) (4)	

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Folder: Adverse Events

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:33:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4)	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 18:51:33

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 18:55:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 18:55:04
Data point term sent to Coder	System	19 Nov 2020 18:53:29
User entered 'muscle aches'	Gerardo Pena (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '7 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:27:08
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '16 Nov 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:27:08
User entered empty.	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'l'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:27:08
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 18:52:37

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Feelings and sensations NEC, PT: Chills, LLT: Chills - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 18:55:06
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 18:55:06
Data point term sent to Coder	System	19 Nov 2020 18:53:30
User entered 'chills'	Gerardo Pena (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '7 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:26:19
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '17 Dec 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:26:19
User entered empty.	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:26:19
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 18:53:29

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:12:52
Query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.'		18 Feb 2021 02:20:11
answered with 'subject entered convalescent period, nasal swab negative for COVID-19' (Site from DM).		
User opened query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		16 Feb 2021 14:07:44
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 18:55:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 18:55:07
Data point term sent to Coder	System	19 Nov 2020 18:54:30
User entered 'fatigue'	Gerardo Pena (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '7 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:49
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
	(b) (4)	
User entered '21 Nov 2020' reason for change: New Information	Gerardo Pena (b) (4)	18 Jan 2021 21:09:33
	(b) (4)	
User entered '23 Dec 2020' reason for change: New Information	Gerardo Pena (b) (4)	18 Jan 2021 21:06:12
	(b) (4)	
User entered '21 Dec 2020' reason for change: New Information	(b) (4), (b) (6)	22 Dec 2020 17:25:49
	(b) (4), (b) (6)	
User entered empty.	Gerardo Pena (b) (4)	19 Nov 2020 18:54:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:54:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
	(b) (4)	
User entered 'Grade 3/Severe (Grade 3/Severe)'	Gerardo Pena (b) (4)	18 Jan 2021 21:06:12
reason for change: New Information	(b) (4)	
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Gerardo Pena (b) (4)	19 Nov 2020 18:54:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:25:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 18:54:23

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 18:56:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 18:56:01
Data point term sent to Coder	System	19 Nov 2020 18:55:36
User entered 'nausea'	Gerardo Pena (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '7 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:39
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '18 Nov 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:39
User entered empty.	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'l'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:24:39
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 18:55:13

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:13:00
Query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.'		18 Feb 2021 02:22:04
answered with 'subject entered convalescent period, nasal swab negative for COVID-19' (Site from DM).		
User opened query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		16 Feb 2021 14:08:14
User closed query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES SECONDARY TO HEAD CONTUSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.'		27 Jan 2021 22:51:37
(Site from DM).		
Query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES SECONDARY TO HEAD CONTUSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify.'		25 Jan 2021 20:46:27
' answered with 'correct as is' (Site from DM).		

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Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this is a worsening of the patient's ongoing Med History condition of HEADACHES SECONDARY TO HEAD CONTUSION. If yes, please update the AE term to reflect the worsening of this condition and ensure that severity is greater than baseline. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:06:20
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:13:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:13:01
Data point term sent to Coder	System	19 Nov 2020 18:56:38
User entered 'headaches'	Gerardo Pena (b) (4)	19 Nov 2020 18:56:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '7 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 12:27:08
Query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:42:13
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:42:05
User opened query 'Per DM CLR: Please review status of this AE as it was noted as ongoing for more than 60 days. Please verify if this AE has resolved and if an End date should be recorded. If yes, please update accordingly. Otherwise, comment to confirm that this AE is still ongoing.' (Site from DM).	(b) (4), (b) (6)	14 Jan 2021 07:58:22
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
	(b) (4)	
User entered '23 Dec 2020' reason for change: New Information	Gerardo Pena (b) (4)	18 Jan 2021 20:42:05
	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	19 Nov 2020 18:56:03
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:56:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:42:05
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4)	19 Nov 2020 18:56:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 18:56:03

US3292259

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 18:56:03

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #10, 11, 12, 13 and 14 (COUGH, SHORTNESS of BREATH, DIFFICULTY BREATHING, SORE THROAT and NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	01 Feb 2021 10:25:32
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #10, 11, 12, 13 and 14 (COUGH, SHORTNESS of BREATH, DIFFICULTY BREATHING, SORE THROAT and NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'no correct as is' (Site from DM).	Dawn Killian (b) (4) (b) (4)	28 Jan 2021 20:37:35
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #10, 11, 12, 13 and 14 (COUGH, SHORTNESS of BREATH, DIFFICULTY BREATHING, SORE THROAT and NASAL CONGESTION), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:06:29
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 18:58:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Nov 2020 18:58:16
Data point term sent to Coder	System	19 Nov 2020 18:57:39
User entered 'fever'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4)	28 Dec 2020 15:55:42
	(b) (4)	
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	19 Nov 2020 18:56:59
	(b) (4)	

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '17 Nov 2020' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 15:55:42
User entered empty.	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	28 Dec 2020 15:55:42
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 18:56:59

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:13:11
Query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.'		18 Feb 2021 02:22:31
answered with 'subject entered convalescent period, nasal swab negative for COVID-19' (Site from DM).		
User opened query 'Per MM, this subject presented with bodyaches, fatigue, headaches (onsets 07Nov2020), and cough (onset 16Nov2020) - please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		16 Feb 2021 14:08:33
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Coughing and associated symptoms, PT: Cough, LLT: Cough - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 19:00:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Nov 2020 19:00:03
Data point term sent to Coder	System	19 Nov 2020 18:58:43
User entered 'cough'	Gerardo Pena (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
	(b) (4)	
User entered 'No (N)' reason for change: New Information	Gerardo Pena (b) (4)	18 Jan 2021 20:53:27
	(b) (4)	
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	19 Nov 2020 18:57:54
	(b) (4)	

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
	(b) (4)	
User entered '22 Dec 2020' reason for change: New Information	Gerardo Pena (b) (4)	18 Jan 2021 20:53:27
	(b) (4)	
User entered empty.	Gerardo Pena (b) (4)	19 Nov 2020 18:57:54
	(b) (4)	

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:57:54
	(b) (4)	

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'l'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 20:53:27
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 18:57:54

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	19 Nov 2020 19:03:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Nov 2020 19:03:02
Data point term sent to Coder	System	19 Nov 2020 19:01:50
User entered 'shortness of breath'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:43
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	28 Dec 2020 16:06:40
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	28 Dec 2020 16:06:40
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	28 Dec 2020 16:06:40
User entered '17 Nov 2020' reason for change: New Information	Gerardo Pena (b) (4)	28 Dec 2020 16:06:40
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	22 Dec 2020 17:15:43
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	22 Dec 2020 17:15:43
User entered empty.	Gerardo Pena (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

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Folder: Adverse Events

Form: Adverse Events (11)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:15:43
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

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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)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Nov 2020 19:01:12

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #11. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #11. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' answered with 'Protocol differentiates these symptoms.' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 12:26:31
User opened query 'Per DM CLR: Please review the dates of this AE as it overlap with the dates of AE #11. Please reconcile and update so there is no overlap or delete duplicate record as applicable. Otherwise, clarify.' (Site from DM).	Gerardo Pena (b) (4)	18 Jan 2021 20:55:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Difficulty breathing - version MedDRA\23.0.	(b) (4), (b) (6)	14 Jan 2021 07:57:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	23 Nov 2020 21:32:00
Data point term sent to Coder	(b) (4)	
User entered 'difficulty breathing'	Coder Import (b) (4)	23 Nov 2020 21:32:00
	System	23 Nov 2020 21:31:31
	Gerardo Pena (b) (4)	23 Nov 2020 21:30:34
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:14:51
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '17 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:14:51
User entered empty.	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:14:51
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 21:30:34

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	23 Nov 2020 21:33:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:33:13
Data point term sent to Coder	System	23 Nov 2020 21:32:31
User entered 'sore throat'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:21
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '21 Nov 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:11:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 21:31:43

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:33:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:33:59
Data point term sent to Coder	System	23 Nov 2020 21:33:32
User entered 'nasal congestion'	Gerardo Pena (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:21
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '17 Nov 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:21
User entered empty.	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:10:21
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 21:32:54

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
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.	(b) (4) Coder Import (b) (4)	23 Nov 2020 21:38:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 21:38:18
Data point term sent to Coder	System	23 Nov 2020 21:36:34
User entered 'diarrhea'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '16 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:35
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '19 Nov 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:35
User entered empty.	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:36:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:09:35
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	23 Nov 2020 21:36:31

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\23.0.	Coder Import (b) (4)	22 Dec 2020 17:06:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Dec 2020 17:06:44
Data point term sent to Coder	System	22 Dec 2020 17:05:55
User entered 'Runny Nose'	(b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '18 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '21 Nov 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	22 Dec 2020 17:06:08
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	22 Dec 2020 17:06:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	22 Dec 2020 17:05:47
User entered '0'	(b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 17:06:08
User entered 'No (N)'		22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	22 Dec 2020 17:06:33
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 17:06:33
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	22 Dec 2020 17:06:33
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 17:05:47
User entered empty.	(b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (16)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Dec 2020 17:05:47

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:06:59
Reviewed for Safety.		19 Jan 2021 18:10:29
User entered	System	19 Jan 2021 18:10:23
'USA-US072-2021-mRNA-1273-P301000006'		
User entered 'New'	(b) (4), (b) (6)	19 Jan 2021 18:10:23

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:00
User coded data point as SOC: Gastrointestinal disorders, HLGT: Abdominal hernias and other abdominal wall conditions, HLT: Abdominal hernias NEC, PT: Abdominal hernia, LLT: Abdominal hernia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Jan 2021 19:02:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	16 Jan 2021 19:02:58
Data point term sent to Coder	System	16 Jan 2021 19:01:35
User entered 'Abdominal Hernia'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:02
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:03
User entered 'No (N)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:05
User entered 'No (N)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:06
User entered '29 Dec 2020'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:08
User entered empty.	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:09
User entered 'No (N)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:11
User entered '29 Dec 2020'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:07:12
User entered empty.	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:14:40
User entered 'Grade 3/Severe (Grade 3/Severe)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:14:42
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:08:11
User entered '0'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:08:14
User entered '0'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:08:15
User entered 'I'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 19:53:31
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 19:19:37
User entered '31 Dec 2020' reason for change: Data Entry Error		30 Apr 2021 19:19:37
DataPoint Verified.		09 Mar 2021 17:08:17
User entered '29 Dec 2020'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 19:53:33
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 19:19:37
User entered '04 Jan 2021' reason for change: Data Entry Error		30 Apr 2021 19:19:37
DataPoint Verified.		09 Mar 2021 17:08:19
User entered '6 Jan 2021'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:08:20
User entered 'No (N)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:08:22
User entered empty.	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:08:24
User entered '0'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:08:25
User entered '0'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:08:27
User entered '0'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:41:03
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 20:57:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Jan 2021 20:57:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:57:26
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Jan 2021 19:01:29
User entered empty.	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	05 Apr 2021 20:41:06
User closed query 'Data is required. Please complete.' (Site from System).	System	18 Jan 2021 20:57:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	18 Jan 2021 20:57:26
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:57:26
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Jan 2021 19:01:29
User entered empty.	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:43:55
User entered 'Not Applicable (NOT APPLICABLE)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:44:06
User entered '0'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'PV Query: Did the subject require treatment with the use of medication? If so, please add medications to CM eCRF page. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:21:08
Query 'PV Query: Did the subject require treatment with the use of medication? If so, please add medications to CM eCRF page. If not, please state so.' answered with 'no' (Site from Safety).	Victoria Hernandez (b) (4)	31 Mar 2021 19:59:46
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:44:07
User opened query 'PV Query: Did the subject require treatment with the use of medication? If so, please add medications to CM eCRF page. If not, please state so.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 16:58:39
User entered '0'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'PV Query: Please provide name and date of surgical procedure.' (Site from Safety).	(b) (4)	01 Apr 2021 18:21:12
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. Per Narrative, SURGERY TO FIX ABDOMINAL HERNIA. Please review and add a Con Procedure as appropriate or update action taken. (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 14:32:40
Query 'PV Query: Please provide name and date of surgical procedure.' answered with 'updated' (Site from Safety).	Victoria Hernandez (b) (4)	31 Mar 2021 20:12:45
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. Per Narrative, SURGERY TO FIX ABDOMINAL HERNIA. Please review and add a Con Procedure as appropriate or update action taken. (Site from DM).	Victoria Hernandez (b) (4)	31 Mar 2021 20:12:40
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:44:10
User opened query 'PV Query: Please provide name and date of surgical procedure.' (Site from Safety).	(b) (4), (b) (6)	26 Jan 2021 16:58:26
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. Per Narrative, SURGERY TO FIX ABDOMINAL HERNIA. Please review and add a Con Procedure as appropriate or update action taken. (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 00:01:59
User entered 'I'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:44:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:44:15
User entered empty.	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 19:00:48
User closed query 'PV Query: Please provide name and date of surgical procedure.' (Site from Safety).		30 Apr 2021 19:00:41
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		30 Apr 2021 19:00:32
User closed query 'PV Query: Please provide the initial signs/symptoms experienced by the subject.' (Site from Safety).		30 Apr 2021 19:00:26
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Medical records have been sent' (Site from Safety).		30 Apr 2021 18:55:03
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Medical records have been sent' (Site from Safety).		30 Apr 2021 18:52:33

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide name and date of surgical procedure.' answered with 'Please see the conprocedure log' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 18:24:52
Query 'PV Query: Please provide the initial signs/symptoms experienced by the subject.' answered with 'Hx of recurrent ventral hernia, abdominal pain' (Site from Safety).		30 Apr 2021 17:58:34
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		08 Apr 2021 15:21:03
User opened query 'PV Query: Please provide name and date of surgical procedure.' (Site from Safety).		08 Apr 2021 15:20:48
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		08 Apr 2021 15:20:41
User opened query 'PV Query: Please provide the initial signs/symptoms experienced by the subject.' (Site from Safety).		08 Apr 2021 15:20:30
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		01 Apr 2021 18:21:31
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).		01 Apr 2021 18:21:28

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the initial signs/symptoms experienced by the subject.' (Site from Safety).	(b) (4), (b) (6)	01 Apr 2021 18:21:22
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results ' (Site from Safety).		01 Apr 2021 18:21:17
Query 'PV Query: Please provide the initial signs/symptoms experienced by the subject.' answered with 'labs sent' (Site from Safety).	Victoria Hernandez (b) (4)	31 Mar 2021 20:16:06
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'labs sent' (Site from Safety).	Victoria Hernandez (b) (4)	31 Mar 2021 20:16:01
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 'labs sent' (Site from Safety).	Victoria Hernandez (b) (4)	31 Mar 2021 20:15:53
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results ' answered with 'labs sent' (Site from Safety).	Victoria Hernandez (b) (4)	31 Mar 2021 20:15:45
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	22 Mar 2021 11:43:37

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:44:19
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).		26 Feb 2021 12:27:14
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. ? ' canceled (Site from Safety).		26 Feb 2021 12:27:09
User opened query 'PV Query: Please provide the initial signs/symptoms experienced by the subject.' (Site from Safety).		22 Feb 2021 18:51:22
Query 'P V Query: Please provide the initial signs/symptoms experienced by the subject. ' canceled (Site from Safety).		26 Jan 2021 17:01:12
User opened query 'P V Query: Please provide the initial signs/symptoms experienced by the subject. ' (Site from Safety).		26 Jan 2021 17:01:06
Query 'P V Query: Please provide the initial signs/symptoms experienced by the subject.' canceled (Site from Safety).		26 Jan 2021 17:00:59
User opened 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).		26 Jan 2021 17:00:44
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.' canceled (Site from Safety)		26 Jan 2021 17:00:36
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results ' (Site from Safety).		26 Jan 2021 16:58:16

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User opened 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 Jan 2021 16:57:55
User opened query 'P V Query: Please provide the initial signs/symptoms experienced by the subject.' (Site from Safety).		26 Jan 2021 16:57:48
User entered 'Pt was contacted via phone to conduct D149 SC, during call, pt reported to have been hospitalized due to abdominal hernia. Pt was admitted on 29Dec2020. Pt was hospitalized for 8 days due to surgery to fix abdominal hernia. Was discharged on 06Jan2021. Will request records.'	Nathan Cortez (b) (4)	16 Jan 2021 19:01:29

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Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (17)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	16 Jan 2021 19:01:29

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:13:27
Query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.'		18 Feb 2021 02:23:49
answered with 'subject entered convalescent period, nasal swab negative for COVID-19' (Site from DM).		
User opened query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		16 Feb 2021 14:08:54
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:14:11
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:14:11
Data point term sent to Coder	System	18 Jan 2021 21:13:56
User entered 'fatigue'	Gerardo Pena (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '23 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'l'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

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Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (18)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Jan 2021 21:13:16

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:13:35
Query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.'		18 Feb 2021 02:24:07
answered with 'subject entered convalescent period, nasal swab negative for COVID-19' (Site from DM).		
User opened query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		16 Feb 2021 14:09:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Muscle disorders, HLT: Muscle pains, PT: Myalgia, LLT: Muscle ache - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:16:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:16:09
Data point term sent to Coder	System	18 Jan 2021 21:14:57
User entered 'muscle aches'	Gerardo Pena (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '23 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 3/Severe (Grade 3/Severe)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'l'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (19)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Jan 2021 21:14:21

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:13:43
Query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.'		18 Feb 2021 02:24:25
answered with 'subject entered convalescent period, nasal swab negative for COVID-19' (Site from DM).		
User opened query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		16 Feb 2021 14:09:28
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal signs and symptoms, HLT: Nausea and vomiting symptoms, PT: Nausea, LLT: Nausea - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:17:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:17:09
Data point term sent to Coder	System	18 Jan 2021 21:15:58
User entered 'nausea'	Gerardo Pena (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '22 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '23 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (20)

Generated On: 09 Jun 2021 16:28:39

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	18 Jan 2021 21:15:35

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	18 Feb 2021 10:13:50
Query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.'		18 Feb 2021 02:24:46
answered with 'subject entered convalescent period, nasal swab negative for COVID-19' (Site from DM).		
User opened query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).		16 Feb 2021 14:10:03
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Difficulty breathing - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:19:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:19:09
Data point term sent to Coder	System	18 Jan 2021 21:18:00
User entered 'difficulty breathing'	Gerardo Pena (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '25 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '26 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

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Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'l'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (21)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Jan 2021 21:17:27

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #23 (RUNNY NOSE), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Apr 2021 10:45:01
Query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #23 (RUNNY NOSE), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' answered with 'correct as is' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	31 Mar 2021 20:16:40
User closed query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:07:18
Query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'subject tested negative for COVID-19.' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 18:10:27
User opened query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 14:10:50

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if this sign/symptom should be combined with AE #23 (RUNNY NOSE), as these have overlapping start/stop dates. Review if these AEs are related and if so combine into one unifying medical diagnosis. Update eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 00:02:19
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Nasal congestion and inflammations, PT: Nasal congestion, LLT: Nasal congestion - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:20:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:20:09
Data point term sent to Coder	System	18 Jan 2021 21:19:00
User entered 'nasal congestion'	Gerardo Pena (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '26 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (22)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Jan 2021 21:18:21

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 12:07:29
Query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' answered with 'subject tested negative for COVID-19.' (Site from DM).	Gerardo Pena (b) (4)	22 Feb 2021 18:10:37
User opened query 'Per MM, this subject presented with fatigue, muscle aches, nausea (onsets 22Dec2020), difficulty breathing (onset 25Dec2020), nasal congestion, runny nose (onsets 26Dec2020)- please confirm if this is a symptom of covid and if the patient was evaluated for potential COVID-19 infection.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 14:11:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:21:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Jan 2021 21:21:12
Data point term sent to Coder	System	18 Jan 2021 21:20:00
User entered 'runny nose'	Gerardo Pena (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '26 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'None (NONE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (23)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	18 Jan 2021 21:19:39

US3292259

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	09 Mar 2021 17:28:11
Reviewed for Safety.	(b) (4), (b) (6)	25 Feb 2021 20:57:06
User entered 'USA-US072-2021-mRNA-1273-P301000006'		25 Feb 2021 20:56:51

US3292259

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:30:42
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Post procedural infection, LLT: Post procedural infection - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	28 Feb 2021 11:12:21
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 11:12:21
Data point term sent to Coder	System	17 Feb 2021 20:57:02
User entered 'Abdominal Hernia Repair Infection'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

US3292259

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:32:32
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

US3292259

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:32:34
User entered 'No (N)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

US3292259

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:32:35
User entered 'No (N)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

US3292259

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:32:37
User entered '02 Feb 2021'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

US3292259

Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:39:28
User entered empty.	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 20:56:49

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 19:01:56
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	30 Apr 2021 17:41:03
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 17:41:03
User entered 'No (N)' reason for change: Per Query Resolution		30 Apr 2021 17:41:03
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	30 Apr 2021 17:40:43
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 18:39:29
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 19:01:59
User closed 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).		30 Apr 2021 19:01:48
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.' answered with 'Updated' (Site from Safety).		30 Apr 2021 17:41:43
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Apr 2021 17:41:34
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	30 Apr 2021 17:41:34
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	30 Apr 2021 17:40:43
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 17:40:43
User entered '18 Feb 2021' reason for change: Per Query Resolution		30 Apr 2021 17:40:43
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	30 Apr 2021 17:03:55
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	30 Apr 2021 17:03:55
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	29 Apr 2021 22:30:41

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	27 Apr 2021 23:08:21
		09 Mar 2021 18:39:31
User entered empty.	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:39:35
User entered empty.	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query '(AE #24) 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)	27 Apr 2021 23:08:25
User opened query '(AE #24) 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).		26 Feb 2021 14:25:57
User entered empty.	System	17 Feb 2021 20:56:49

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:39:37
User entered 'Grade 4 (Grade 4)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:39:41
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

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[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:39:54
User entered '0'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:39:56
User entered '0'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per CDM: Thank you for your response. Kindly update the Hospital Discharge Date once the data is available.' (Site from DM).	(b) (4)	28 Apr 2021 11:07:38
Query 'Per CDM: Thank you for your response. Kindly update the Hospital Discharge Date once the data is available.' answered with 'Updated discharge date' (Site from DM).	(b) (4), (b) (6)	7 Apr 2021 22:09:05
DataPoint Verified.		9 Mar 2021 18:41:56
User opened query 'Per CDM: Thank you for your response. Kindly update the Hospital Discharge Date once the data is available.' (Site from DM).		8 Feb 2021 15:25:51
User closed 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).		8 Feb 2021 15:24:37
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.' answered with 'Patient has not dc' (Site from System).	Nathan Cortez (b) (4)	17 Feb 2021 20:57:18
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	17 Feb 2021 20:56:49
User entered 'I'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 19:49:49
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 22:08:46
User entered '13 Feb 2021' reason for change: Data Entry Error		27 Apr 2021 22:08:46
DataPoint Verified.		09 Mar 2021 18:41:51
User entered '12 Feb 2021'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 19:49:52
DataPoint Un-verified.	(b) (4), (b) (6)	27 Apr 2021 22:08:46
User entered '18 Feb 2021' reason for change: New Information		27 Apr 2021 22:08:46
DataPoint Verified.		09 Mar 2021 18:41:52
User entered empty.	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:41:53
User entered 'No (N)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:41:57
User entered empty.	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:42:00
User entered '0'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:42:01
User entered '0'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:42:03
User entered '0'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:42:04
User entered 'Not Related (NOT RELATED)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:42:06
User entered 'Not Related (NOT RELATED)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 18:00:18
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 21:48:22
User entered 'Not Applicable (NOT APPLICABLE)'		29 Apr 2021 21:48:22
reason for change: Per Query Resolution		09 Mar 2021 18:42:15
DataPoint Verified.		
User entered 'None (NONE)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 18:00:12
User closed query '(AE #24) PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).		30 Apr 2021 16:28:03
Query '(AE #24) PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' answered with 'Updated' (Site from Safety).		29 Apr 2021 21:50:38
User closed query 'None is checked, but Concomitant System Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).		29 Apr 2021 21:48:22
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 21:48:22
User opened query 'None is checked, but Concomitant Medication or Concomitant Procedure is also checked. Please correct.' (Site from System).	System	29 Apr 2021 21:45:51
DataPoint Un-verified.	(b) (4), (b) (6)	29 Apr 2021 21:45:51
User entered '1' reason for change: Data Entry Error		29 Apr 2021 21:45:51
DataPoint Verified.		09 Mar 2021 18:42:28
User opened query '(AE #24) PV Query: As the subject received both doses of mRNA-1273 or placebo prior to the onset of the event, please consider updating the action taken to not applicable.' (Site from Safety).		26 Feb 2021 14:25:20
User entered '0'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 11:57:18
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Updated' (Site from DM).		29 Apr 2021 21:50:50
DataPoint Verified.		09 Mar 2021 18:42:29
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		02 Mar 2021 04:47:11
User entered 'I'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant 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)	30 Apr 2021 11:57:21
Query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.' answered with 'Updated' (Site from DM).		29 Apr 2021 22:21:05
DataPoint Verified.		09 Mar 2021 18:42:31
User opened query 'Per DM CLR: Other Action Taken = Con Procedure, however there is no therapeutic Concomitant 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).		02 Mar 2021 04:46:55
User entered 'I'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 19:18:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	30 Apr 2021 17:41:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Per Query Resolution		30 Apr 2021 17:03:55
Query '(AE #24) PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).		30 Apr 2021 16:28:26
DataPoint Un-verified.		29 Apr 2021 22:30:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Per Query Resolution		29 Apr 2021 22:30:41
DataPoint Verified.		09 Mar 2021 18:42:33
User opened query '(AE #24) PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		26 Feb 2021 14:26:40
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 18:42:38
User entered empty.	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 19:52:35
DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 19:40:36
User entered 'PHONE CALL TO SUBJECT TO ASSESS DAY 179 SC, SUBJECT INFORMED SITE THAT SHE IS CURRENTLY IN THE HOSPITAL. SUBJECT WAS ADMITTED TO METHODIST METROPOLITAN ON 2/12/21 FOR DRAINING FROM WHERE HER ABDOMINAL HERNIA WAS REPAIRED. SHE WAS TOLD THAT IT IS A SEVERE INFECTION AND THAT IT WOULD NEED TO BE DRAINED. IV ANTIBIOTICS WERE STARTED ON 2/12/21 BUT SUBJECT STATES THAT HER IV WAS NOT PLACED CORRECTLY AND SHE WAS NOT RECEIVING ANY OF THE MEDICATION. A NEW IV WAS STARTED AND SHE IS NOW RECEIVING MEDICATION. A PROCEDURE TO DRAIN THE PUSS THAT WAS DRAINING FROM HER ABDOMINAL HERNIA WAS DONE ON 2/15/21 WITH THE POSSIBILITY OF ANOTHER ROUND OF DRAINING PENDING THE OUTCOME OF THE FIRST PROCEDURE. SHE DOES NOT KNOW THE NAME OF MEDICATIONS SHE IS BEING GIVEN, SITE DID ADVISE HER THAT WE WOULD REQUEST RECORDS AND SHE AGREED. SHE WAS ADVISED TO CALL US WITH ANY CHANGES OR CONCERNS. SUBJECT WAS ALSO TESTED FOR COVID 19 ON 2/12/21 WITH A NEGATIVE RESULT. CONMED LOG WILL BE UPDATED WHEN WE RECEIVE MEDICAL RECORDS . Subject had reported being admitted to the hospital on 12Feb. However, medical records state that admission date was 13Feb2021' reason for change: Data Entry Error		30 Apr 2021 19:40:36

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Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	30 Apr 2021 18:48:57
User closed query '(AE #24) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		30 Apr 2021 18:48:53
Query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'Med Records emailed' (Site from Safety).		30 Apr 2021 17:44:12
Query '(AE #24) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' answered with 'Med records sent email' (Site from Safety).		30 Apr 2021 17:43:36
User closed query '(AE #24) 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).' (Site from Safety).		30 Apr 2021 16:28:09

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[Narrative](#)

Audit	User	Time (GMT)
Query '(AE #24) 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).' answered with 'Updated con med/ con procedures' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 22:24:37
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		22 Mar 2021 11:42:27
DataPoint Verified.		09 Mar 2021 18:43:23
User opened query '(AE #24) PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		26 Feb 2021 14:27:41
User opened query '(AE #24) 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).' (Site from Safety).		26 Feb 2021 14:27:01

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'Phone call to subject to assess day 179 SC, subject informed site that she is currently in the hospital. Subject was admitted to Methodist Metropolitan on 2/12/21 for draining from where her abdominal hernia was repaired. She was told that it is a severe infection and that it would need to be drained. IV antibiotics were started on 2/12/21 but subject states that her IV was not placed correctly and she was not receiving any of the medication. A new IV was started and she is now receiving medication. A procedure to drain the puss that was draining from her abdominal hernia was done on 2/15/21 with the possibility of another round of draining pending the outcome of the first procedure. She does not know the name of medications she is being given, site did advise her that we would request records and she agreed. She was advised to call us with any changes or concerns. Subject was also tested for Covid 19 on 2/12/21 with a negative result. Conmed log will be updated when we receive medical records .'	Nathan Cortez (b) (4)	17 Feb 2021 20:56:49

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	17 Feb 2021 20:56:49

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Folder: Adverse Events

Form: Adverse Events (24)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 20:56:49

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: General disorders and administration site conditions, HLGT: Administration site reactions, HLT: Injection site reactions, PT: Injection site pain, LLT: Pain injection site - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	08 Apr 2021 17:41:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Apr 2021 17:41:57
Data point term sent to Coder	System	08 Apr 2021 17:40:27
User entered 'Pain at Injection Site'	Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '28 Jan 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing. Please review & update accordingly, else clarify' (Site from DM).	(b) (4), (b) (6)	30 Apr 2021 11:57:45
Query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing. Please review & update accordingly, else clarify' answered with 'Updated' (Site from DM).		29 Apr 2021 20:26:03
User entered '16:00' reason for change: Per Query Resolution		29 Apr 2021 20:22:17
User opened query 'Per CDM: As per CCG, Start time is required for an AE that starts within 24 hours of dosing. Please review & update accordingly, else clarify' (Site from DM).		12 Apr 2021 09:06:43
User closed query 'Data is required. Please provide.' (Site from System).		12 Apr 2021 09:06:30
Query 'Data is required. Please provide.' answered with 'Only required for SAEs' (Site from System).	Nathan Cortez (b) (4)	08 Apr 2021 17:40:35
User opened query 'Data is required. Please provide.' (Site from System).	System	08 Apr 2021 17:40:16
User entered empty.	Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '28 Jan 2021 16:00'	System	29 Apr 2021 20:22:17
User entered empty.	System	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

Persistent or significant disability or incapacity

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Related (RELATED)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Related (RELATED)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (25)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 17:40:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Tooth fracture, LLT: Tooth fracture - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 03:03:36
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Apr 2021 03:03:36
Data point term sent to Coder	System	08 Apr 2021 17:42:30
User entered 'Broken Bottom Incisor'	Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '29 Dec 2020'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '20 Mar 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Related (NOT RELATED)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (26)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 17:42:16

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain, LLT: Abdominal pain - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	29 Apr 2021 22:45:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Apr 2021 22:45:12
Data point term sent to Coder	System	29 Apr 2021 22:44:23
User entered 'Abdominal Pain'	(b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	30 Apr 2021 16:55:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 16:55:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 16:55:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 22:43:59
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	30 Apr 2021 16:55:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	30 Apr 2021 16:55:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Apr 2021 16:55:56
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 22:43:59
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	29 Apr 2021 22:43:59

US3292259

Folder: Adverse Events

Form: Adverse Events (27)

Generated On: 09 Jun 2021 16:28:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	29 Apr 2021 22:43:59

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:28:39

Were any prior/concomitant medications and/or vaccinations taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User closed query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on day 2, day 3 and day 5 Subject states he took Tylenol (500 mg) for fever Kindly update Tylenol in the concomitant medication page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Nov 2020 10:35:22
Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on day 2, day 3 and day 5 Subject states he took Tylenol (500 mg) for fever Kindly update Tylenol in the concomitant medication page. Thank you. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	23 Sep 2020 21:04:23
User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on day 2, day 3 and day 5 Subject states he took Tylenol (500 mg) for fever Kindly update Tylenol in the concomitant medication page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 19:34:13
Query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on day 1, day 2 and day 4 Subject states he took Tylenol (500 mg) for fever Kindly update Tylenol in the concomitant medication page. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 19:34:04
User opened query 'Per CDM: Per the participant response, medication was taken to treat pain or fever is yes on day 1, day 2 and day 4 Subject states he took Tylenol (500 mg) for fever Kindly update Tylenol in the concomitant medication page. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 Sep 2020 19:29:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	24 Aug 2020 12:59:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: OTHER ANTIMIGRAINE PREPARATIONS, PRODUCT: TOPIRAMATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Aug 2020 13:01:33
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 13:01:33
Data point term sent to Coder	System	24 Aug 2020 13:00:39
User entered 'TOPIRAMATE'	(b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'HEADACHE'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '50'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '09 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:00:26

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/APAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 13:04:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 13:04:31
Data point term sent to Coder	System	24 Aug 2020 13:03:41
User entered 'hydrocodone/APAP'	(b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'low back pain'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '10-325'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'un UNK 1998'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	24 Aug 2020 13:03:17

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Aug 2020 13:05:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Aug 2020 13:05:35
Data point term sent to Coder	System	24 Aug 2020 13:04:42
User entered 'januvia'	(b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'diabetes type II'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '50'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'un Nov 2019'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	24 Aug 2020 13:03:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Sep 2020 21:20:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 21:20:40
Data point term sent to Coder	System	23 Sep 2020 21:19:25
User entered 'tylenol'	Dawn Killian (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 14:12:16
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' answered with 'this was diary? no AE needed' (Site from DM).	Dawn Killian (b) (4) (b) (4)	13 Apr 2021 17:57:07
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF if appropriate. ' (Site from DM).	(b) (4), (b) (6)	17 Dec 2020 19:02:48
User entered 'mild fever'	Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '500'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mg (mg)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'as needed (PRN)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Oral (ORAL)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '21 Aug 2020'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '25 Aug 2020'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User closed query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). Query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' answered with 'updated' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 00:45:09
User entered 'No (N)' reason for change: Data Entry Error	Kevin Martinez (b) (4) (b) (4)	05 Nov 2020 23:31:14
User opened query 'Per DM CLR: Note, Was this medication taken for solicited event?' = Yes. However, associated condition is not a Solicited Adverse Reaction per Protocol section 8.3.4. Review and update entry as appropriate.' (Site from DM). User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4) (b) (4), (b) (6)	05 Nov 2020 23:31:06 01 Nov 2020 08:52:05
	Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Sep 2020 21:18:53

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Nov 2020 21:20:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:20:09
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:05:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Nov 2020 21:05:10
Data point term sent to Coder Coding entries removed.	System Kevin Martinez (b) (4)	05 Nov 2020 23:33:42 05 Nov 2020 23:33:06
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: ANTIINFLAMMATORY AGENTS, ATC: CORTICOSTEROIDS, PLAIN, PRODUCT: PREDNISOLONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	24 Sep 2020 05:13:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Sep 2020 05:13:46
Data point term sent to Coder User entered 'Prednisolone Eye Drops 1 %'	System Dawn Killian (b) (4)	23 Sep 2020 21:24:45 23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'eye infection'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'I'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Other (OTHER)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'drop'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'twice daily (BID)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 00:44:48
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.'	Kevin Martinez (b) (4)	05 Nov 2020 23:33:12
answered with 'updated' (Site from DM).	(b) (4)	
User entered 'Other (OTHER)' reason for change:	Kevin Martinez (b) (4)	05 Nov 2020 23:33:06
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated (consider Other: Ophthalmic). Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 03:45:22
User entered 'Intraocular (INTRAOCULAR)'	Dawn Killian (b) (4)	23 Sep 2020 21:24:19
	(b) (4)	

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Ophthalmic' reason for change: Data Entry Error	(b) (4) Kevin Martinez (b) (4)	05 Nov 2020 23:33:06
User entered empty.	(b) (4) Dawn Killian (b) (4)	23 Sep 2020 21:24:19
	(b) (4)	

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '01 Sep 2020'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4)	
	Dawn Killian (b) (4)	23 Sep 2020 21:24:19
	(b) (4)	

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
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)	
' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 10:48:56
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.		20 Apr 2021 14:47:58
' answered with 'Updated' (Site from DM).		
User entered 'No (N)' reason for change: Data Entry Error		20 Apr 2021 14:47:51
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.		17 Dec 2020 19:03:03
' (Site from DM).		
User entered 'Yes (Y)'	Dawn Killian (b) (4)	23 Sep 2020 21:24:19
	(b) (4)	

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '17 Sep 2020' reason for change: New Information	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:47:51
User entered empty.	Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User entered '2'	System	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User entered 'l'		23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:38
Data hard unlocked.		02 May 2021 04:23:29
Data hard locked.		02 May 2021 04:23:10
User entered '804 (804)'	System	23 Sep 2020 21:24:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Nov 2020 03:56:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Nov 2020 03:56:12
Data point term sent to Coder	System	23 Nov 2020 21:41:46
User entered 'baclofen'	Gerardo Pena (b) (4) (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'muscle soreness'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '10'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'once daily (QD)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '7 Nov 2020'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '16 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Apr 2021 14:56:00
User entered empty.	Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User entered 'I'	System	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User entered 'I'	System	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:43
User entered '804 (804)'	System	23 Nov 2020 21:41:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	15 Dec 2020 21:39:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	15 Dec 2020 21:39:56
Data point term sent to Coder	System	15 Dec 2020 21:38:31
User entered 'shingles vaccine'	Gerardo Pena (b) (4)	15 Dec 2020 21:38:15
	(b) (4)	

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'shingles'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0.5'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mL (mL)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Apr 2021 15:49:28
User entered empty.	Gerardo Pena (b) (4) (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'once (ONCE)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '6 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '6 Dec 2020'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User entered empty.	System	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User entered empty.	System	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:28:49
User entered empty.	System	15 Dec 2020 21:38:15

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 22:55:03
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 22:55:03
Data point term sent to Coder	System	22 Feb 2021 22:54:03
User entered 'Atorvastatin'	Gerardo Pena (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Apr 2021 10:47:26
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'Updated' (Site from DM).		20 Apr 2021 14:59:23
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).		07 Apr 2021 05:03:45
User entered 'hypercholesterolemia'	Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '10'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mg (mg)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'once daily (QD)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Oral (ORAL)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '15 Aug 2020'	(b) (4) Gerardo Pena (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Gerardo Pena (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Feb 2021 22:53:29

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: BACLOFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 20:48:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 20:48:57
Data point term sent to Coder	System	08 Apr 2021 17:33:14
User entered 'Baclofen'	Nathan Cortez (b) (4) (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Muscle Aches'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '10'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mg (mg)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'once daily (QD)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Oral (ORAL)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '07 Nov 2020'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 17:32:55

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: VARICELLA ZOSTER VACCINES, PRODUCT: VARICELLA ZOSTER VACCINE - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 17:35:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	08 Apr 2021 17:35:55
Data point term sent to Coder	System	08 Apr 2021 17:35:17
User entered 'Shingles Vaccine'	Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Prophylaxis'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0.5'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mL (mL)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'once (ONCE)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '06 Dec 2020'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '06 Dec 2020'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User entered empty.	System	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User entered empty.	System	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:29:05
User entered empty.	System	08 Apr 2021 17:35:07

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 17:36:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 17:36:43
Data point term sent to Coder	System	08 Apr 2021 17:36:20
User entered 'Tylenol'	Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Pain at Injection Site'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '500'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'mg (mg)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'as needed (PRN)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Oral (ORAL)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '28 Jan 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered '0'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 17:36:19

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME HYDROCHLORIDE, PRODUCTSYNONYM: CEFEPIME HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 23:37:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 23:37:30
Data point term sent to Coder	System	29 Apr 2021 20:33:38
User entered 'Cefepime HCL'	(b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:07:14
User entered 'Yes (Y)'		29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '2'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Q12Hr'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:32:49

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
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)	30 Apr 2021 05:14:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:14:33
Data point term sent to Coder	System	29 Apr 2021 20:35:39
User entered 'Metronidazole'	(b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:07:35
User entered 'Yes (Y)'		29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '100'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'QHR'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:35:08

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 06:31:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:31:17
Data point term sent to Coder	System	29 Apr 2021 20:37:40
User entered 'VANCOMYCIN' reason for change:	(b) (4), (b) (6)	29 Apr 2021 20:37:39
Data Entry Error		
User entered 'Vanocomycin'		29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:07:53
User entered 'Yes (Y)'		29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '1500'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'ut dict'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:37:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 20:41:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 20:41:02
Data point term sent to Coder	System	29 Apr 2021 20:40:42
User entered 'Acetaminophen'	(b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:08:09
User entered 'Yes (Y)'		29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '650'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:40:09

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN;HYDROCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 04:31:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 04:31:19
Data point term sent to Coder	System	29 Apr 2021 20:41:43
User entered 'Hydrocodone-Acetaminophen'	(b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:08:36
User entered 'Yes (Y)'		29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '5/325'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:41:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: MAGNESIUM SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 05:10:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:10:15
Data point term sent to Coder	System	29 Apr 2021 20:44:44
User entered 'Magnesium Sulfate'	(b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	29 Apr 2021 22:08:54
User entered 'Yes (Y)'	(b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '100'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'ut dict'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:44:18

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: MORPHINE SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 05:38:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:38:12
Data point term sent to Coder	System	29 Apr 2021 20:45:45
User entered 'Morphine Sulfate'	(b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
	(b) (4)	
User entered 'No (N)' reason for change: New Information	(b) (4), (b) (6)	29 Apr 2021 22:11:32
User entered 'Yes (Y)'		29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '2'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 20:49:04
User entered '18 Feb 2021'		29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:45:24

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: MAGNESIUM COMPOUNDS, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 05:09:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:09:15
Data point term sent to Coder	System	29 Apr 2021 20:46:46
User entered 'Magnesium Oxide'	(b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:12:56
User entered 'Yes (Y)'		29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '800'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'ut dict'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:46:44

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTION ADDITIVES, ATC: ELECTROLYTE SOLUTIONS, PRODUCT: POTASSIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 06:00:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:00:13
Data point term sent to Coder	System	29 Apr 2021 20:48:49
User entered 'Potassium Chloride'	(b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:11:02
User entered 'Yes (Y)'		29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '100'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'ut dict'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:48:28

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 06:14:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 06:14:29
Data point term sent to Coder	System	29 Apr 2021 20:52:52
User entered 'Sodium Chloride'	(b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:10:49
User entered 'Yes (Y)'		29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '1000'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Q10Hr'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '16 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:51:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: MAGNESIUM COMPOUNDS, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 05:09:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 05:09:15
Data point term sent to Coder	System	29 Apr 2021 20:57:55
User entered 'Magnesium Oxide'	(b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:10:17
User entered 'Yes (Y)'		29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '800'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'ut dict'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'feeding tube'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:56:57

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON HCL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 21:00:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Apr 2021 21:00:06
Data point term sent to Coder	System	29 Apr 2021 20:59:13
User entered 'Ondansetron HCl'	(b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:10:00
User entered 'Yes (Y)'		29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '4'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'ut dict'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 20:58:30

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: THIRD-GENERATION CEPHALOSPORINS, PRODUCT: CEFTRIAXONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	29 Apr 2021 23:02:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	29 Apr 2021 23:02:16
Data point term sent to Coder	System	29 Apr 2021 21:00:15
User entered 'Ceftriaxone'	(b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:09:38
User entered 'Yes (Y)'		29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'ut dict'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:00:14

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 04:24:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 04:24:18
Data point term sent to Coder	System	29 Apr 2021 21:04:19
User entered 'Glucagon'	(b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:09:24
User entered 'Yes (Y)'		29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'l'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'ut dict'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:04:04

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Apr 2021 04:25:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 04:25:18
Data point term sent to Coder	System	29 Apr 2021 21:42:44
User entered 'Humalog'	(b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Apr 2021 22:09:10
User entered 'Yes (Y)'		29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '2'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Sliding Scale'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4) System	29 Apr 2021 21:43:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Apr 2021 21:43:04
User entered 'as needed (PRN)' reason for change: Per Query Resolution	(b) (4), (b) (6)	29 Apr 2021 21:43:04
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Apr 2021 21:42:42
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '18 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Apr 2021 21:42:42

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE, PRODUCTSYNONYM: FLAGYL [METRONIDAZOLE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 May 2021 13:49:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:49:34
Data point term sent to Coder	System	30 Apr 2021 18:23:19
User entered 'Flagyl'	(b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '500'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 18:22:52

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: CIPROFLOXACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	01 May 2021 13:46:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 May 2021 13:46:38
Data point term sent to Coder	System	30 Apr 2021 18:24:20
User entered 'Ciprofloxacin'	(b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Abdominal Hernia Repair Infection'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '500'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '17 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '0'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '26 Feb 2021'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 16:28:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	30 Apr 2021 18:24:06

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:28:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:25
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:49:28
User closed query 'Please update to "yes" and add abdominal hernia surgery to con-procedures.' (Site from CRA).	(b) (4)	21 Apr 2021 16:48:55
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 16:48:54
Query 'Please update to "yes" and add abdominal hernia surgery to con-procedures.' answered with 'updated' (Site from CRA).	Victoria Hernandez (b) (4)	31 Mar 2021 20:15:01
Signature has been broken.	(b) (4)	
	Victoria Hernandez (b) (4)	31 Mar 2021 20:13:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Victoria Hernandez (b) (4)	31 Mar 2021 20:13:10
User opened query 'Please update to "yes" and add abdominal hernia surgery to con-procedures.' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 16:56:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered 'No (N)'	Dawn Killian (b) (4)	04 Feb 2021 16:50:41
	(b) (4)	

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '29 Dec 2020'	(b) (4) Victoria Hernandez (b) (4)	31 Mar 2021 20:14:10

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Ventral Hernia Repair'	(b) (4) Victoria Hernandez (b) (4)	31 Mar 2021 20:14:10

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Adverse Event (AE)'	(b) (4) Victoria Hernandez (b) (4)	31 Mar 2021 20:14:10

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:39

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	31 Mar 2021 20:14:10

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '29 Dec 2020'	(b) (4) Victoria Hernandez (b) (4)	31 Mar 2021 20:14:50

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Exploratory Laparotomy'	(b) (4) Victoria Hernandez (b) (4)	31 Mar 2021 20:14:50

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Adverse Event (AE)'	(b) (4) Victoria Hernandez (b) (4)	31 Mar 2021 20:14:50

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:39

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	31 Mar 2021 20:14:50

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '20 Mar 2021'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:43:31

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:28:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Broken Incisor Repair'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:43:31

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'Adverse Event (AE)'	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:43:31

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:28:39

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered empty.	(b) (4) Nathan Cortez (b) (4)	08 Apr 2021 17:43:31

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '13 Feb 2021'	(b) (4), (b) (6)	29 Apr 2021 22:19:48

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:28:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Cat Scan - Abdomen/Pelvis'	(b) (4), (b) (6)	29 Apr 2021 22:19:48

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Apr 2021 22:19:48

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 16:28:39

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:19:48

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '15 Feb 2021'	(b) (4), (b) (6)	29 Apr 2021 22:20:36

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:28:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Ultrasound guided Needle Aspiration'	(b) (4), (b) (6)	29 Apr 2021 22:20:36

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	29 Apr 2021 22:20:36

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 16:28:39

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 17:59:51
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered empty.	(b) (4), (b) (6)	29 Apr 2021 22:20:36

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:20:15

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:28:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Omentectomy'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:20:15

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:20:15

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 16:28:39

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:20:15

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:20:39

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:28:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Removal of Fb'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:20:39

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:20:39

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 16:28:39

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:20:39

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:28:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '29 Dec 2020'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:08

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:28:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Bilat Myocut Flaps'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:08

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:28:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:08

US3292259

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 16:28:39

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered empty.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 18:21:08

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:28:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '19/Jan/2021 13:10'	(b) (4) System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:28:39

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)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'l'		19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:28:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered '18/Feb/2021 14:27'	(b) (4) System	18 Feb 2021 19:27:59

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:28:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:50:52
DataPoint Verified.		09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
User entered 'l'	(b) (4), (b) (6)	18 Feb 2021 19:27:59

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:28:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:16:46
User entered '25/Feb/2021 15:57'	(b) (4) System	25 Feb 2021 20:57:47

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:28:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 13:50:52
DataPoint Verified.		09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:16:46
User entered 'l'	(b) (4) (b) (4), (b) (6)	25 Feb 2021 20:57:47

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:28:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:45:23
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered '01/Apr/2021 09:53'	(b) (4) System	01 Apr 2021 16:53:12

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:28:39

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)	30 Apr 2021 18:45:23
Reviewed for Safety.		30 Apr 2021 13:50:52
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:21:51
User entered 'l'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 16:53:12

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:28:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 18:45:25
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered '30/Apr/2021 09:51'	(b) (4) System	30 Apr 2021 13:51:19

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:28:39

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)	30 Apr 2021 18:45:25
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 13:51:19

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:28:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:54:08
User entered '30/Apr/2021 14:49'	System	30 Apr 2021 18:49:36

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:28:39

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.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 19:54:08
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 18:49:36

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:28:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 19:54:09
User entered '30/Apr/2021 15:02'	System	30 Apr 2021 19:02:27

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:28:39

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.	Douglas Denham (b) (4)	03 May 2021 14:18:49
DataPoint Verified.	(b) (4)	30 Apr 2021 19:54:09
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 19:02:27

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'USA-US072-2021-MRNA-1273-P301000006'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Yes (Y)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'No (N)'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Douglas'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'Denham'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '7940 Floyd Curl Drive'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered 'San Antonio'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 18:10:42
User entered '78229'	System	19 Jan 2021 18:10:23

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:25:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 19:27:40
User entered 'US'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE-USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	03 May 2021 13:24:53
User entered '7'	System	30 Apr 2021 19:02:27
User entered '6'	System	30 Apr 2021 18:49:36
User entered '5'	System	30 Apr 2021 13:51:19
User entered '4'	System	01 Apr 2021 16:53:12
Signature has been broken.	System	25 Feb 2021 20:57:47
User entered '3'	System	25 Feb 2021 20:57:47
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:29:54
	(b) (4)	
User entered '2'	System	18 Feb 2021 19:27:59
User entered '1'	System	19 Jan 2021 18:10:51

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:28:39

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered '03/May/2021 09:24'	(b) (4) System	03 May 2021 13:24:53

US3292259

Folder: SAE USA-US072-2021-MRNA-1273-P301000006

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:28:39

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.	Douglas Denham (b) (4)	03 May 2021 14:18:49
User entered 'I'	(b) (4) (b) (4), (b) (6)	03 May 2021 13:24:53