

US3292173 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:27:36

All time stamps listed in this document are displayed in GMT

US3292173

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

[Participant ID](#)

US3292173

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

US3292173

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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 19:57:51

Generated On: 09 Jun 2021 16:27:36

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	61
Age Units	YEARS
Age (Derived)	61
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 19:57:51

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Date of Informed Consent (<i>dd MMM yyyy</i>)	13 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 19:57:51

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 19:57:51

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 19:57:51

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Condition	RHINITIS
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	RUPTURED APPENDIX
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	WISDOM TEETH REMOVAL
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	MOUTH PAIN
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1981
Start Year (derived)	1981
Stop Month and Year (derived)	JAN 1981
Stop Year (derived)	1981

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	INTESTINAL BLOCKAGE
Start date (dd MMM yyyy)	UN UNK 2016
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 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	LEFT KNEE ANTERIOR CRUCIATE LIGAMENT TEAR
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 (8)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	LEFT KNEE MEDIAL COLLATERAL LIGAMENT TEAR
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 (9)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	LEFT KNEE SURGERY
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 (10)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	TONSIL INFECTION
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1995
Start Year (derived)	1995
Stop Month and Year (derived)	JAN 1995
Stop Year (derived)	1995

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	APPENDICITIS
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1973
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 1973
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1973
Start Year (derived)	1973
Stop Month and Year (derived)	JAN 1973
Stop Year (derived)	1973

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	ERECTILE DYSFUNCTION
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Condition	ACID REFLUX
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Start Year (derived)	2004
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	15:47 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:47
Height (xxx.x)	180.3 cm
Weight (xxx.x)	94.2 kg
BMI (xxx.x)	28.97740 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:57:51

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Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

13 AUG 2020

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

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:57:51

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☒ No ☐

Specify

HVAC CONTRACTOR

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 19:57:51

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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 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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 19:57:51

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What was the date of randomization? (dd MMM yyyy) 13 AUG 2020

What was the participant's randomization number? 104157

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 19:57:51

Generated On: 09 Jun 2021 16:27:36

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 19:57:51

Generated On: 09 Jun 2021 16:27:36

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)	13 AUG 2020
Time of assessment (00:00-23:59)	15:47 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 15:47
Temperature (xxx.x)	35.8 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)	15 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 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 19:57:51

Generated On: 09 Jun 2021 16:27:36

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input type="radio"/> Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 AUG 2020
Time of assessment (00:00-23:59)	18:07 (24 HR)
Vital Signs Date and Time (derived)	13 AUG 2020 18:07
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)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	94 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 19:57:51

Generated On: 09 Jun 2021 16:27:36

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: Exposure

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

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) 13 AUG 2020

What was the treatment time? (00:00-23:59) 17:27 (24 HR)

Treatment Date and Time (derived) 13 AUG 2020 17:27

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 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	13 AUG 2020
Collection time (00:00-23:59)	16:00 (24 HR)
Collection date and time (derived)	13 AUG 2020 16:00

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)			13 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:08	13 AUG 2020 16:08
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

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 16:27:36

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 AUG 2020 18:17

PC Open Date & Time

13 AUG 2020 17:47

PC Close Date & Time

13 AUG 2020 20:17

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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 13 AUG 2020 21:54

PC Open Date & Time 13 AUG 2020 21:12

PC Close Date & Time 14 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

14 AUG 2020 21:14

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

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

16 AUG 2020 05:59

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

16 AUG 2020 17:05

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

97.3 °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

17 AUG 2020 21:00

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

97.3 °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

18 AUG 2020 19:10

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

95.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

19 AUG 2020 16:48

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

13 AUG 2020 18:18

PC Open Date & Time

13 AUG 2020 17:47

PC Close Date & Time

13 AUG 2020 20:17

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

13 AUG 2020 21:55

PC Open Date & Time

13 AUG 2020 21:12

PC Close Date & Time

14 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

14 AUG 2020 21:13

PC Open Date & Time

14 AUG 2020 12:00

PC Close Date & Time

15 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

16 AUG 2020 05:59

PC Open Date & Time

15 AUG 2020 12:00

PC Close Date & Time

16 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

16 AUG 2020 17:03

PC Open Date & Time

16 AUG 2020 12:00

PC Close Date & Time

17 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

17 AUG 2020 21:00

PC Open Date & Time

17 AUG 2020 12:00

PC Close Date & Time

18 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

18 AUG 2020 19:10

PC Open Date & Time

18 AUG 2020 12:00

PC Close Date & Time

19 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

19 AUG 2020 16:49

PC Open Date & Time

19 AUG 2020 12:00

PC Close Date & Time

20 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 18:18
PC Open Date & Time	13 AUG 2020 17:47
PC Close Date & Time	13 AUG 2020 20:17

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

No ☒

Yes ☐

PC Time stamp	13 AUG 2020 21:55
PC Open Date & Time	13 AUG 2020 21:12
PC Close Date & Time	14 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

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 ☒

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	14 AUG 2020 21:14
PC Open Date & Time	14 AUG 2020 12:00
PC Close Date & Time	15 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

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 ☒

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 05:58
PC Open Date & Time	15 AUG 2020 12:00
PC Close Date & Time	16 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

60 of 2130

EAB) (1725)

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	16 AUG 2020 17:03
PC Open Date & Time	16 AUG 2020 12:00
PC Close Date & Time	17 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

62 of 2130

EAB) (1725)

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	17 AUG 2020 21:00
PC Open Date & Time	17 AUG 2020 12:00
PC Close Date & Time	18 AUG 2020 11:59

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

64 of 2130

EAB) (1725)

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

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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US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	19 AUG 2020 16:49
PC Open Date & Time	19 AUG 2020 12:00
PC Close Date & Time	20 AUG 2020 11:59

US3292173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

3 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 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

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

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)	12 SEP 2020
Time of assessment (00:00-23:59)	10:32 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 10:32
Temperature (xxx.x)	36.2 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)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

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)	12 SEP 2020
Time of assessment (00:00-23:59)	12:06 (24 HR)
Vital Signs Date and Time (derived)	12 SEP 2020 12:06
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	61 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	123 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3292173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 SEP 2020

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

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

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) 12 SEP 2020

What was the treatment time? (00:00-23:59) 11:36 (24 HR)

Treatment Date and Time (derived) 12 SEP 2020 11:36

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

US3292173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 SEP 2020
Collection time (00:00-23:59)	10:42 (24 HR)
Collection date and time (derived)	12 SEP 2020 10:42

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)			12 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:55	12 SEP 2020 10:55
Nasopharyngeal Swab 2	No		

US3292173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

12 SEP 2020 12:11

PC Open Date & Time

12 SEP 2020 11:56

PC Close Date & Time

12 SEP 2020 14:26

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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 97.0 °F

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

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

PC Time Stamp	12 SEP 2020 22:40
PC Open Date & Time	12 SEP 2020 15:21
PC Close Date & Time	13 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

13 SEP 2020 17:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

15 SEP 2020 06:16

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

15 SEP 2020 19:30

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 07:03

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 16:16

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

18 SEP 2020 15:02

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

12 SEP 2020 12:11

PC Open Date & Time

12 SEP 2020 11:56

PC Close Date & Time

12 SEP 2020 14:26

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

12 SEP 2020 22:37

PC Open Date & Time

12 SEP 2020 15:21

PC Close Date & Time

13 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

13 SEP 2020 17:24

PC Open Date & Time

13 SEP 2020 12:00

PC Close Date & Time

14 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

15 SEP 2020 06:16

PC Open Date & Time

14 SEP 2020 12:00

PC Close Date & Time

15 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

15 SEP 2020 19:30

PC Open Date & Time

15 SEP 2020 12:00

PC Close Date & Time

16 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

17 SEP 2020 07:01

PC Open Date & Time

16 SEP 2020 12:00

PC Close Date & Time

17 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

17 SEP 2020 16:15

PC Open Date & Time

17 SEP 2020 12:00

PC Close Date & Time

18 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

18 SEP 2020 15:02

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 12:12
PC Open Date & Time	12 SEP 2020 11:56
PC Close Date & Time	12 SEP 2020 14:26

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

No ☒

Yes ☐

PC Time stamp	12 SEP 2020 22:37
PC Open Date & Time	12 SEP 2020 15:21
PC Close Date & Time	13 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	13 SEP 2020 17:24
PC Open Date & Time	13 SEP 2020 12:00
PC Close Date & Time	14 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

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)

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 06:16
PC Open Date & Time	14 SEP 2020 12:00
PC Close Date & Time	15 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

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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US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	15 SEP 2020 19:31
PC Open Date & Time	15 SEP 2020 12:00
PC Close Date & Time	16 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 07:01
PC Open Date & Time	16 SEP 2020 12:00
PC Close Date & Time	17 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

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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US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	17 SEP 2020 16:15
PC Open Date & Time	17 SEP 2020 12:00
PC Close Date & Time	18 SEP 2020 11:59

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

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EAB) (1725)

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 15:01
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3292173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted? Yes ☒
No ☐

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

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

Comments ONE ATTEMPT WAS MADE,
UNSUCCESSFUL , VISIT NOT
COMPLETE
If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

28 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

5 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	13 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

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	13 OCT 2020
Time of assessment (00:00-23:59)	13:27 (24 HR)
Vital Signs Date and Time (derived)	13 OCT 2020 13:27
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

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.

US3292173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

13 OCT 2020

Collection time (00:00-23:59)

13:35 (24 HR)

Collection date and time (derived)

13 OCT 2020 13:35

US3292173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:52

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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	13 OCT 2020 06:14:56
Patient Cloud Open Date & Time	13 OCT 2020 00:01
Patient Cloud Close Date & Time	17 OCT 2020 23:59

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	22 OCT 2020 12:01:44
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 OCT 2020 09:04:34
Patient Cloud Open Date & Time	27 OCT 2020 00:01
Patient Cloud Close Date & Time	31 OCT 2020 23:59

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 NOV 2020 14:20:36

Patient Cloud Open Date & Time

10 NOV 2020 00:01

Patient Cloud Close Date & Time

14 NOV 2020 23:59

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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	17 NOV 2020 07:01:59
Patient Cloud Open Date & Time	17 NOV 2020 00:01
Patient Cloud Close Date & Time	21 NOV 2020 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

23 NOV 2020 18:02:51

Patient Cloud Open Date & Time

21 NOV 2020 00:01

Patient Cloud Close Date & Time

25 NOV 2020 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 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	29 NOV 2020 19:24:38
Patient Cloud Open Date & Time	28 NOV 2020 00:01
Patient Cloud Close Date & Time	02 DEC 2020 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 DEC 2020 14:00:11

Patient Cloud Open Date & Time

05 DEC 2020 00:01

Patient Cloud Close Date & Time

09 DEC 2020 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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	12 DEC 2020 06:04:12
Patient Cloud Open Date & Time	12 DEC 2020 00:01
Patient Cloud Close Date & Time	16 DEC 2020 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 DEC 2020 07:38:15
Patient Cloud Open Date & Time	19 DEC 2020 00:01
Patient Cloud Close Date & Time	23 DEC 2020 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 DEC 2020 07:40:32

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 JAN 2021 10:36:49

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 JAN 2021 11:06:07

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 JAN 2021 21:24:15

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 05:50:24
Patient Cloud Open Date & Time	23 JAN 2021 00:01
Patient Cloud Close Date & Time	27 JAN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

30 JAN 2021 05:41:06

Patient Cloud Open Date & Time

30 JAN 2021 00:01

Patient Cloud Close Date & Time

03 FEB 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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	09 FEB 2021 08:05:07
Patient Cloud Open Date & Time	06 FEB 2021 00:01
Patient Cloud Close Date & Time	10 FEB 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	13 FEB 2021 11:47:31
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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	20 FEB 2021 13:00:07
Patient Cloud Open Date & Time	20 FEB 2021 00:01
Patient Cloud Close Date & Time	24 FEB 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 FEB 2021 13:33:38

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

06 MAR 2021 15:27:41

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

16 MAR 2021 06:18:34

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 07:18:09

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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	27 MAR 2021 06:51:58
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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	04 APR 2021 18:23:21
Patient Cloud Open Date & Time	03 APR 2021 00:01
Patient Cloud Close Date & Time	07 APR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

10 APR 2021 07:35:36

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

17 APR 2021 20:59:32

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

24 APR 2021 08:55:40

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	01 MAY 2021 20:11:14
Patient Cloud Open Date & Time	01 MAY 2021 00:01
Patient Cloud Close Date & Time	05 MAY 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 <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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 <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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 334

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 <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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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="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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JAN 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

02 FEB 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐ Yes ☐

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

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

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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13 JUL 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

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US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

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US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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24 AUG 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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31 AUG 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 <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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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14 SEP 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

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28 SEP 2022 23:59

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 <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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2022 23:59

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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"/>

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:27:36

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		27 FEB 2021 13:33:57

US3292173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

11 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:11:37

Generated On: 09 Jun 2021 16:27:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	12 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:11:37

Generated On: 09 Jun 2021 16:27:36

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3292173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:11:37

Generated On: 09 Jun 2021 16:27:36

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.

US3292173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:11:37

Generated On: 09 Jun 2021 16:27:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

12 MAR 2021

Collection time (00:00-23:59)

08:36 (24 HR)

Collection date and time (derived)

12 MAR 2021 08:36

US3292173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:11:37

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

8 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292173

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:27:36

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3292173

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 FEB 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	UNBLND_DECIDE

US3292173

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

Form: Unblinding

Data signed: (b) (4) 28 Apr 2021 13:36:48

Generated On: 09 Jun 2021 16:27:36

Date of updated informed consent (dd MMM yyyy)	9 FEB 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)	9 FEB 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

US3292173

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

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

US3292173

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

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)	9 FEB 2021
Time of assessment (00:00-23:59)	08:25 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 08:25
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3292173

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

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)	9 FEB 2021
Time of assessment (00:00-23:59)	10:40 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 10:40
Temperature (xxx.x)	36.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	122 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3292173

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 FEB 2021

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

US3292173

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

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

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) 9 FEB 2021

What was the treatment time? (00:00-23:59) 10:09 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 10:09

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

US3292173

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

9 FEB 2021

Collection time (00:00-23:59)

08:36 (24 HR)

Collection date and time (derived)

9 FEB 2021 08:36

US3292173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	9 FEB 2021
Collection time (00:00 - 23:59)	09:30
Collection Date and Time (derived)	9 FEB 2021 09:30

US3292173

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 19:57:51

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	9 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

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

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)	9 MAR 2021
Time of assessment (00:00-23:59)	08:13 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 08:13
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	73 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	136 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	85 mmHg
Diastolic Blood Pressure units	MMHG

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

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)	9 MAR 2021
Time of assessment (00:00-23:59)	09:59 (24 HR)
Vital Signs Date and Time (derived)	9 MAR 2021 09:59
Temperature (xxx.x)	36.3 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	86 mmHg
Diastolic Blood Pressure units	MMHG

US3292173

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

9 MAR 2021

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

US3292173

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

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) 9 MAR 2021

What was the treatment time? (00:00-23:59) 09:29 (24 HR)

Treatment Date and Time (derived) 9 MAR 2021 09:29

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

What was the frequency of the study treatment dosing? ONCE

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

US3292173

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292173

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292173

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	5 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

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Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

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Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

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: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:06:04

Generated On: 09 Jun 2021 16:27:36

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

5 APR 2021

Collection time (00:00-23:59)

08:50 (24 HR)

Collection date and time (derived)

5 APR 2021 08:50

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Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 03 May 2021 14:18:42

Generated On: 09 Jun 2021 16:27:36

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 03 May 2021 20:04:28

Generated On: 09 Jun 2021 16:27:36

AEID	
Adverse event	VASOVAGAL SYNCOPE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 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)	09 FEB 2021
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 (1)

Data signed: (b) (4) 03 May 2021 20:04:28

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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 type="radio"/> Not Applicable <input checked="" 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 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 (2)

Data signed: (b) (4) 03 May 2021 20:04:28

Generated On: 09 Jun 2021 16:27:36

AEID	USA-US072-2021-MRNA-1273-P30 1000022
Adverse event	CHOLECYSTITIS
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 APR 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)	28 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	28 APR 2021
Hospital Discharge Date (dd MMM yyyy)	30 APR 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 (2)

Data signed: (b) (4) 03 May 2021 20:04:28

Generated On: 09 Jun 2021 16:27:36

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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 (2)

Data signed: (b) (4) 03 May 2021 20:04:28

Generated On: 09 Jun 2021 16:27:36

SUBJECT STATED HE HAD AN
EMERGENCY
CHOLECYSTECTOMY FOR
CHOLECYSTITIS ON 28 APR 2021
AND WAS ADMITTED FOR 2
NGHTS @ NORTH CENTRAL
BAPTIST. TRAMADOL 50MG PO
PRN. WAS PRESCRIBED AT
DISCHARGE FOR PAIN.

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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

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) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication RHINITIS (ALLERGIC)

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 (1)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	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 2004	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication OMEPREZOLE

Prophylaxis Yes ☐
No ☒

Indication ACID REFLUX

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	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 2004	
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 (3)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication NIACIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 250

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) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	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 APR 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 (4)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication MULTI VITAMIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

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 ☐
Intraocular ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	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	1980
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 (5)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication METAMUCIL (PSYLLIUM HUSK POWDER)

Prophylaxis Yes ☒
No ☐

Indication DIGESTIVE HEALTH

Dose per administration 2

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

If dose unit is Other, specify SCOOPS

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 (6)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	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)	UN	UNK 2004
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication GENERALIZED MUSCLE ACHES

Dose per administration 400

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication TADALAFIL

Prophylaxis Yes ☐
No ☒

Indication ERECTILE DYSFUNCTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	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 2009	
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"/>

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA

Dose per administration .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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	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)		27 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)		27 SEP 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"/>

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

Name of Medication _____

Prophylaxis Yes ☐
No ☐

Indication _____

Dose per administration _____

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

If dose unit is Other, specify _____

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

If frequency is Other, specify _____

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 29 Apr 2021 17:56:38

Generated On: 09 Jun 2021 16:27:36

	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) _____		
Start date completely unknown _____		
Ongoing?	Yes	<input type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input 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"/>

US3292173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 19:57:50

Generated On: 09 Jun 2021 16:27:36

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

US3292173

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:27:36

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

US3292173

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:27:36

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 ☐

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 20:04:28

Generated On: 09 Jun 2021 16:27:36

SAEID	USA-US072-2021-MRNA-1273-P301000022
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)	1

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 20:04:28

Generated On: 09 Jun 2021 16:27:36

SAEID	USA-US072-2021-MRNA-1273-P301000022
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)	1
Date of submission (Pre-filled from custom function)	03/MAY/2021 14:59
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

US3292173 (Prod: Clinical Trials of Texas, Inc)

US3292173

Form: Participant Creation

Generated On: 09 Jun 2021 16:27:36

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:15:43
User entered 'US3292173'	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:59:11

US3292173

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:45:42

US3292173

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:59:12

US3292173

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[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 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:45:42

US3292173

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'SCRN'	System	15 Aug 2020 01:45:42

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:59:13

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '61'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'YEARS'	System	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '61'	System	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'l'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:27:36

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:05

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Aug 2020'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Aug 2020'	System	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2020'	System	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Amendment 2 (2)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:29

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 21:59:12

US3292173

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:27:36

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'l'	System	13 Aug 2020 22:50:33

US3292173

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:33

US3292173

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:27:36

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:28

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Rhinitis, LLT: Rhinitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	15 Aug 2020 01:49:07
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	15 Aug 2020 01:49:07
Data point term sent to Coder	System	15 Aug 2020 01:47:55
User entered 'Rhinitis'	(b) (4), (b) (6)	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1986'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1986'	System	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1986'	System	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered empty.	System	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered empty.	System	15 Aug 2020 01:46:54

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 02:02:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 02:02:10
Data point term sent to Coder	System	15 Aug 2020 02:01:04
User entered 'Appendectomy'	(b) (4), (b) (6)	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1973'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1973'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1973'	System	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1973'	System	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1973'	System	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1973'	System	15 Aug 2020 02:01:00

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis perforated, LLT: Ruptured appendix - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	15 Aug 2020 02:03:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 02:03:10
Data point term sent to Coder	System	15 Aug 2020 02:02:05
User entered 'Ruptured appendix'	(b) (4), (b) (6)	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1973'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1973'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1973'	System	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1973'	System	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1973'	System	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1973'	System	15 Aug 2020 02:01:26

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 02:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 02:04:10
Data point term sent to Coder	System	15 Aug 2020 02:03:06
User entered 'Wisdom teeth removal'	(b) (4), (b) (6)	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1981'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1981'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1981'	System	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1981'	System	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1981'	System	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1981'	System	15 Aug 2020 02:02:17

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Oral soft tissue conditions, HLT: Oral soft tissue signs and symptoms, PT: Oral pain, LLT: Mouth pain - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 02:04:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	15 Aug 2020 02:04:10
Data point term sent to Coder	System	15 Aug 2020 02:03:06
User entered 'Mouth Pain'	(b) (4), (b) (6)	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1981'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1981'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4), (b) (6)	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1981'	System	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1981'	System	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1981'	System	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1981'	System	15 Aug 2020 02:02:42

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Intestinal obstruction, LLT: Intestinal obstruction - version MedDRA\23.0.	(b) (4) Coder Import (b) (4)	15 Aug 2020 07:27:07
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Aug 2020 07:27:07
Data point term sent to Coder	System	15 Aug 2020 02:07:09
User entered 'Intestinal blockage'	(b) (4), (b) (6)	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 2016'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 2016'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2016'	System	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2016'	System	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2016'	System	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2016'	System	15 Aug 2020 02:06:11

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Anterior cruciate ligament tear - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:20:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:20:20
Data point term sent to Coder	System	16 Aug 2020 02:11:58
User entered 'Left Knee Anterior Cruciate Ligament Tear'	(b) (4), (b) (6)	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'UN UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2017'	System	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2017'	System	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2017'	System	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2017'	System	16 Aug 2020 02:11:01

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Muscle, tendon and ligament injuries, PT: Ligament rupture, LLT: Ligament tear - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 07:05:35
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 07:05:35
Data point term sent to Coder	System	16 Aug 2020 02:11:59
User entered 'Left Knee Medial Collateral Ligament Tear'	(b) (4), (b) (6)	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2017'	System	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2017'	System	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2017'	System	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2017'	System	16 Aug 2020 02:11:41

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 02:17:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 02:17:25
Data point term sent to Coder	System	16 Aug 2020 02:17:01
Coding entries removed.	(b) (4), (b) (6)	16 Aug 2020 02:16:47
User entered 'LEFT KNEE SURGERY' reason for change: Data Entry Error	(b) (4), (b) (6)	16 Aug 2020 02:16:47
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 02:13:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 02:13:26
Data point term sent to Coder	System	16 Aug 2020 02:12:59
User entered 'Knee Surgery'	(b) (4), (b) (6)	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 2017'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2017'	System	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2017'	System	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2017'	System	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2017'	System	16 Aug 2020 02:12:45

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 02:15:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:15:24
Data point term sent to Coder	System	16 Aug 2020 02:14:00
User entered 'Tonsillectomy'	(b) (4), (b) (6)	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1995'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1995'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1995'	System	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1995'	System	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1995'	System	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1995'	System	16 Aug 2020 02:13:28

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 06:38:05
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 06:38:05
Data point term sent to Coder	System	16 Aug 2020 02:15:00
User entered 'Tonsil infection'	(b) (4), (b) (6)	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1995'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1995'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1995'	System	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1995'	System	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1995'	System	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1995'	System	16 Aug 2020 02:14:39

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Abdominal and gastrointestinal infections, PT: Appendicitis, LLT: Appendicitis - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	16 Aug 2020 02:17:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:17:25
Data point term sent to Coder	System	16 Aug 2020 02:16:01
User entered 'Appendicitis'	(b) (4), (b) (6)	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1973'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1973'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1973'	System	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1973'	System	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1973'	System	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1973'	System	16 Aug 2020 02:15:42

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendicectomy, LLT: Appendectomy - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 02:17:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	16 Aug 2020 02:17:25
Data point term sent to Coder	System	16 Aug 2020 02:17:01
User entered 'Appendectomy'	(b) (4), (b) (6)	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1973'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 1973'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1973'	System	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1973'	System	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 1973'	System	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '1973'	System	16 Aug 2020 02:16:03

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Sexual function and fertility disorders, HLT: Erection and ejaculation conditions and disorders, PT: Erectile dysfunction, LLT: Erectile dysfunction - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:19:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	16 Aug 2020 02:19:25
Data point term sent to Coder	System	16 Aug 2020 02:18:01
User entered 'Erectile Dysfunction'	(b) (4), (b) (6)	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Un UNK 2009'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2009'	System	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2009'	System	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered empty.	System	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered empty.	System	16 Aug 2020 02:17:56

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: Acid reflux (esophageal) - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	21 Sep 2020 18:16:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	21 Sep 2020 18:16:45
Data point term sent to Coder	System	21 Sep 2020 18:16:01
User entered 'Acid Reflux'	Dawn Killian (b) (4)	21 Sep 2020 18:15:08
	(b) (4)	

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'UN UNK 2004'	(b) (4) Dawn Killian (b) (4)	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) Dawn Killian (b) (4)	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Dawn Killian (b) (4)	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) Dawn Killian (b) (4)	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'Jan 2004'	System	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '2004'	System	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered empty.	System	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered empty.	System	21 Sep 2020 18:15:08

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Per CDM: Response noted; however Time is required. Please refer to CCGs page 23 for more details. Thank you.' (Site from DM).	(b) (4)	
Query 'Per CDM: Response noted; however Time is required. Please refer to CCGs page 23 for more details. Thank you.' answered with 'UPDATED' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 13:36:17
Query 'Per CDM: Response noted; however Time is required. Please refer to CCGs page 23 for more details. Thank you.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	22 Sep 2020 18:18:01
User entered '15:47' reason for change: Data Entry Error	(b) (4)	
User closed query 'Data is required. Please provide.' (Site from System).	Victoria Hernandez (b) (4)	22 Sep 2020 18:17:27
User opened query 'Per CDM: Response noted; however Time is required. Please refer to CCGs page 23 for more details. Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 13:18:29
Query 'Data is required. Please provide.' answered with 'Combined visit' (Site from System).		24 Aug 2020 13:18:23
User opened query 'Data is required. Please provide.' (Site from System).		16 Aug 2020 02:25:17
User entered empty.	System	16 Aug 2020 02:25:07
	(b) (4), (b) (6)	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered '13 Aug 2020 15:47'	System	22 Sep 2020 18:17:27
User entered empty.	System	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '180.3' cm	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07
DataPoint set to visible.	System	13 Aug 2020 22:50:33

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '94.2' kg	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07
DataPoint set to visible.	System	13 Aug 2020 22:50:33

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
Amendment Manager: User entered '28.97740'	System	16 Sep 2020 23:56:30
User entered '29.0'	System	16 Aug 2020 02:25:07
DataPoint set to visible.	System	13 Aug 2020 22:50:33

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'kg/m2'	System	16 Aug 2020 02:25:07
DataPoint set to visible.	System	13 Aug 2020 22:50:33

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Per CDM RQ: Please remove responses from the data field "Route of measurement and If Other, specify" by leaving them blank as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 07:14:27
Query 'Per CDM RQ: Please remove responses from the data field "Route of measurement and If Other, specify" by leaving them blank as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	05 Nov 2020 18:45:19
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4) (b) (4)	05 Nov 2020 18:45:12
User opened query 'Per CDM RQ: Please remove responses from the data field "Route of measurement and If Other, specify" by leaving them blank as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:20:29
User closed query 'Per CDM: Please remove data as this field should be blank. ' (Site from DM).		05 Nov 2020 18:20:29
Query 'Per CDM: Please remove data as this field should be blank. ' answered with 'nd' (Site from DM).		07 Oct 2020 17:57:32
User opened query 'Per CDM: Please remove data as this field should be blank. ' (Site from DM).		07 Oct 2020 16:32:48
User entered 'Other (Other)'		16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty; reason for change Data Entry Error	(b) (4)	
	Dawn Killian (b) (4)	05 Nov 2020 18:45:12
User closed query 'Per CDM: Please remove data as this field should be blank.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please remove data as this field should be blank.' answered with 'updated' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 18:20:50
User opened query 'Per CDM: Please remove data as this field should be blank.' (Site from DM).		07 Oct 2020 17:57:28
User entered missing code ND - Not Done.		07 Oct 2020 16:32:04
		16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'bpm'	System	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'breaths/min'	System	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'mmHg'	System	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User entered 'mmHg'	System	16 Aug 2020 02:25:07

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35

US3292173

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35

US3292173

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:37:34

US3292173

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4), (b) (6)	13 Sep 2020 16:06:29
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		12 Sep 2020 17:46:36
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 02:37:34

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

[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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'HVAC Contractor'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

[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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'l'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:27:36

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 21:17:35
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:20:07

US3292173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:37:49

US3292173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Aug 2020'	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:37:49

US3292173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[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 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	16 Aug 2020 02:37:49

US3292173

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'VISIT1'	System	16 Aug 2020 02:37:49

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 22:19:22

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4) System	21 Aug 2020 04:24:04
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 04:24:04
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	13 Aug 2020 22:19:22
User entered '104157' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 22:19:22

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	13 Aug 2020 22:19:22

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

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 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:38:24

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

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 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:38:24

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:38:24

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:38:24

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:38:24

US3292173

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:27:36

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 10:20:32
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:11:42

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User accepted default value 'Pre-Dose (PREDOSE)'		16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '15:47'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '13 Aug 2020 15:47'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Oct 2020 13:43:04
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS per INV' (Site from System).	Dawn Killian (b) (4) (b) (4)	21 Sep 2020 18:11:53
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:56:30
User entered '35.8' C	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '70'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'bpm'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '15'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'breaths/min'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '130'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '85'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User accepted default value 'Post-Dose (POSTDOSE)'		16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4)	(b) (4), (b) (6)
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'as per protocol post dose vitals can be completed 30 minutes after dosing' (Site from System).		17 Aug 2020 18:48:51
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		16 Aug 2020 02:29:37
User entered '18:07'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '13 Aug 2020 18:07'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '36.4' C	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '62'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'bpm'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'breaths/min'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '136'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '94'	(b) (4), (b) (6)	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	16 Aug 2020 02:28:44

US3292173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:38:01

US3292173

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 02:38:01

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

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 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'MRNA-1273 OR PLACEBO'	System	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Aug 2020'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '17:27'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '13 Aug 2020 17:27'	System	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Nathan Cortez (b) (4)	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'ONCE'	System	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'INTRAMUSCULAR'	System	13 Aug 2020 22:50:54

US3292173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:32:07

US3292173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 02:32:07

US3292173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '16:00'	(b) (4), (b) (6)	16 Aug 2020 02:32:07

US3292173

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '13 Aug 2020 16:00'	System	16 Aug 2020 02:32:07

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Aug 2020'	(b) (4), (b) (6)	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	(b) (4), (b) (6)	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '16:08'	(b) (4), (b) (6)	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '13 Aug 2020 16:08'	System	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:36

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered empty.	System	16 Aug 2020 02:36:10

US3292173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	16 Aug 2020 02:39:03

US3292173

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'l'	System	16 Aug 2020 02:39:03

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:16:43', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4fc01910-fd22-493a-9fd6-623ae9312d63' User entered 'Yes (Y)'	System	13 Aug 2020 23:17:30
	System	13 Aug 2020 23:17:30

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:16:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4fc01910-fd22-493a-9fd6-623ae9312d63' User entered '97.6'	System	13 Aug 2020 23:17:30
	System	13 Aug 2020 23:17:30

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:16:57', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4fc01910-fd22-493a-9fd6-623ae9312d63'	System	13 Aug 2020 23:17:30
User entered 'No (N)'	System	13 Aug 2020 23:17:30

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:17:26', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4fc01910-fd22-493a-9fd6-623ae9312d63'	System	13 Aug 2020 23:17:30
User entered '13 Aug 2020 18:17'	System	13 Aug 2020 23:17:30

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 17:47'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 20:17'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:54:02', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1bae8cce-8665-48f4-a762-ebb2ec691d2b' User entered 'Yes (Y)'	System	14 Aug 2020 02:54:52
	System	14 Aug 2020 02:54:52

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:54:42', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1bae8cce-8665-48f4-a762-ebb2ec691d2b' User entered '96.8'	System	14 Aug 2020 02:54:52
	System	14 Aug 2020 02:54:52

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:54:47', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1bae8cce-8665-48f4-a762-ebb2ec691d2b' User entered 'No (N)'	System	14 Aug 2020 02:54:52
	System	14 Aug 2020 02:54:52

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:54:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1bae8cce-8665-48f4-a762-ebb2ec691d2b' User entered '13 Aug 2020 21:54'	System	14 Aug 2020 02:54:52
	System	14 Aug 2020 02:54:52

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 21:12'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 2'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:14:19', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd6e0b221-db19-491e-9d68-9d790a5c5a05'	System	15 Aug 2020 02:14:37
User entered 'Yes (Y)'	System	15 Aug 2020 02:14:37

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:14:26', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd6e0b221-db19-491e-9d68-9d790a5c5a05' User entered '96.9'	System	15 Aug 2020 02:14:37
	System	15 Aug 2020 02:14:37

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:14:31', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd6e0b221-db19-491e-9d68-9d790a5c5a05'	System	15 Aug 2020 02:14:37
User entered 'No (N)'	System	15 Aug 2020 02:14:37

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:14:34', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd6e0b221-db19-491e-9d68-9d790a5c5a05' User entered '14 Aug 2020 21:14'	System	15 Aug 2020 02:14:37
	System	15 Aug 2020 02:14:37

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 3'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:59:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '590c121b-8853-44ce-a6a9-f917bdd02932'	System	16 Aug 2020 10:59:58
User entered 'Yes (Y)'	System	16 Aug 2020 10:59:58

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:59:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '590c121b-8853-44ce-a6a9-f917bdd02932' User entered '95.1'	System	16 Aug 2020 10:59:58
	System	16 Aug 2020 10:59:58

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:59:54', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '590c121b-8853-44ce-a6a9-f917bdd02932'	System	16 Aug 2020 10:59:58
User entered 'No (N)'	System	16 Aug 2020 10:59:58

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:59:57', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '590c121b-8853-44ce-a6a9-f917bdd02932'	System	16 Aug 2020 10:59:58
User entered '16 Aug 2020 05:59'	System	16 Aug 2020 10:59:58

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 4'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:23', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '448d355c-198d-498d-ac65-ac0c3976d1a0' User entered 'Yes (Y)'	System	16 Aug 2020 22:05:10
	System	16 Aug 2020 22:05:10

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:04:41', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '448d355c-198d-498d-ac65-ac0c3976d1a0' User entered '96.9'	System	16 Aug 2020 22:05:10
	System	16 Aug 2020 22:05:10

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:05:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '448d355c-198d-498d-ac65-ac0c3976d1a0' User entered 'No (N)'	System	16 Aug 2020 22:05:10
	System	16 Aug 2020 22:05:10

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:05:09', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '448d355c-198d-498d-ac65-ac0c3976d1a0' User entered '16 Aug 2020 17:05'	System	16 Aug 2020 22:05:10
	System	16 Aug 2020 22:05:10

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 5'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T20:59:46', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7db2e96b-21fb-4c65-85d5-2cd0a5309a4e' User entered 'Yes (Y)'	System	18 Aug 2020 02:00:04
	System	18 Aug 2020 02:00:04

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T20:59:51', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7db2e96b-21fb-4c65-85d5-2cd0a5309a4e' User entered '97.3'	System	18 Aug 2020 02:00:04
	System	18 Aug 2020 02:00:04

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T20:59:57', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7db2e96b-21fb-4c65-85d5-2cd0a5309a4e' User entered 'No (N)'	System	18 Aug 2020 02:00:04
	System	18 Aug 2020 02:00:04

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7db2e96b-21fb-4c65-85d5-2cd0a5309a4e' User entered '17 Aug 2020 21:00'	System	18 Aug 2020 02:00:04
	System	18 Aug 2020 02:00:04

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 6'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:31', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1416073d-b40a-444f-879e-0f30fec8403a'	System	19 Aug 2020 00:10:45
User entered 'Yes (Y)'	System	19 Aug 2020 00:10:45

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:36', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1416073d-b40a-444f-879e-0f30fec8403a' User entered '97.3'	System	19 Aug 2020 00:10:45
	System	19 Aug 2020 00:10:45

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:39', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1416073d-b40a-444f-879e-0f30fec8403a'	System	19 Aug 2020 00:10:45
User entered 'No (N)'	System	19 Aug 2020 00:10:45

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:41', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1416073d-b40a-444f-879e-0f30fec8403a' User entered '18 Aug 2020 19:10'	System	19 Aug 2020 00:10:45
	System	19 Aug 2020 00:10:45

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 7'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:48:39', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7f78cfec-1893-4b2a-8ff9-8a213cb0b76e' User entered 'Yes (Y)'	System	19 Aug 2020 21:48:54
	System	19 Aug 2020 21:48:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:48:44', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7f78cfec-1893-4b2a-8ff9-8a213cb0b76c' User entered '95.8'	System	19 Aug 2020 21:48:54
	System	19 Aug 2020 21:48:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:48:47', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7f78cfec-1893-4b2a-8ff9-8a213cb0b76e' User entered 'No (N)'	System	19 Aug 2020 21:48:54
	System	19 Aug 2020 21:48:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:48:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7f78cfee-1893-4b2a-8ff9-8a213cb0b76e' User entered '19 Aug 2020 16:48'	System	19 Aug 2020 21:48:54
	System	19 Aug 2020 21:48:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:17:38', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1e54a7e3-6a4f-4502-ba3f-b9a4b237e87d' User entered 'None (1)'	System	13 Aug 2020 23:18:06
	System	13 Aug 2020 23:18:06

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:17:42', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1e54a7e3-6a4f-4502-ba3f-b9a4b237e87d' User entered 'No (N)'	System	13 Aug 2020 23:18:06
	System	13 Aug 2020 23:18:06

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:17:49', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1e54a7e3-6a4f-4502-ba3f-b9a4b237e87d' User entered 'No (N)'	System	13 Aug 2020 23:18:06
	System	13 Aug 2020 23:18:06

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:17:58', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1e54a7e3-6a4f-4502-ba3f-b9a4b237e87d' User entered 'None (1)'	System	13 Aug 2020 23:18:06
	System	13 Aug 2020 23:18:06

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:04', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '1e54a7e3-6a4f-4502-ba3f-b9a4b237e87d' User entered '13 Aug 2020 18:18'	System	13 Aug 2020 23:18:06
	System	13 Aug 2020 23:18:06

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 17:47'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 20:17'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:03', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd0411fe1-76ce-4c7f-82fa-bcd46c15d1f7'	System	14 Aug 2020 02:55:23
User entered 'None (1)'	System	14 Aug 2020 02:55:23

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd0411fe1-76ce-4c7f-82fa-bcd46c15d1f7'	System	14 Aug 2020 02:55:23
User entered 'No (N)'	System	14 Aug 2020 02:55:23

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:11', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd0411fe1-76ce-4c7f-82fa-bcd46c15d1f7'	System	14 Aug 2020 02:55:23
User entered 'No (N)'	System	14 Aug 2020 02:55:23

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:17', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd0411fe1-76ce-4c7f-82fa-bcd46c15d1f7'	System	14 Aug 2020 02:55:23
User entered 'None (1)'	System	14 Aug 2020 02:55:23

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:20', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd0411fe1-76ce-4c7f-82fa-bcd46c15d1f7'	System	14 Aug 2020 02:55:23
User entered '13 Aug 2020 21:55'	System	14 Aug 2020 02:55:23

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 21:12'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 2'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:09', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '11556f21-94b5-4cf3-8f8b-c8e4833754cc'	System	15 Aug 2020 02:13:33
User entered 'None (1)'	System	15 Aug 2020 02:13:33

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:13', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '11556f21-94b5-4cf3-8f8b-c8e4833754cc' User entered 'No (N)'	System	15 Aug 2020 02:13:33
	System	15 Aug 2020 02:13:33

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:19', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '11556f21-94b5-4cf3-8f8b-c8e4833754cc'	System	15 Aug 2020 02:13:33
User entered 'No (N)'	System	15 Aug 2020 02:13:33

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:27', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '11556f21-94b5-4cf3-8f8b-c8e4833754cc'	System	15 Aug 2020 02:13:33
User entered 'None (1)'	System	15 Aug 2020 02:13:33

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:30', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '11556f21-94b5-4cf3-8f8b-c8e4833754cc' User entered '14 Aug 2020 21:13'	System	15 Aug 2020 02:13:33
	System	15 Aug 2020 02:13:33

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 3'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:59', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '878862d5-6ab4-4b5d-a3c2-74cd26a7a6eb' User entered 'None (1)'	System	16 Aug 2020 10:59:19
	System	16 Aug 2020 10:59:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:59:10', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '878862d5-6ab4-4b5d-a3c2-74cd26a7a6eb' User entered 'No (N)'	System	16 Aug 2020 10:59:19
	System	16 Aug 2020 10:59:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:59:12', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '878862d5-6ab4-4b5d-a3c2-74cd26a7a6eb' User entered 'No (N)'	System	16 Aug 2020 10:59:19
	System	16 Aug 2020 10:59:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:59:14', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '878862d5-6ab4-4b5d-a3c2-74cd26a7a6eb' User entered 'None (1)'	System	16 Aug 2020 10:59:19
	System	16 Aug 2020 10:59:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:59:18', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '878862d5-6ab4-4b5d-a3c2-74cd26a7a6eb' User entered '16 Aug 2020 05:59'	System	16 Aug 2020 10:59:19
	System	16 Aug 2020 10:59:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 4'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd8710d9e-3d01-47bd-adf1-5793277bc8a6' User entered 'None (1)'	System	16 Aug 2020 22:03:19
	System	16 Aug 2020 22:03:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:11', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd8710d9e-3d01-47bd-adf1-5793277bc8a6' User entered 'No (N)'	System	16 Aug 2020 22:03:19
	System	16 Aug 2020 22:03:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:13', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd8710d9e-3d01-47bd-adf1-5793277bc8a6' User entered 'No (N)'	System	16 Aug 2020 22:03:19
	System	16 Aug 2020 22:03:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:15', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd8710d9e-3d01-47bd-adf1-5793277bc8a6' User entered 'None (1)'	System	16 Aug 2020 22:03:19
	System	16 Aug 2020 22:03:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:17', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd8710d9e-3d01-47bd-adf1-5793277bc8a6' User entered '16 Aug 2020 17:03'	System	16 Aug 2020 22:03:19
	System	16 Aug 2020 22:03:19

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 5'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:03', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8f85e070-5a78-4121-a5db-10dcba0005c2'	System	18 Aug 2020 02:00:16
User entered 'None (1)'	System	18 Aug 2020 02:00:16

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:06', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8f85e070-5a78-4121-a5db-10dcba0005c2'	System	18 Aug 2020 02:00:16
User entered 'No (N)'	System	18 Aug 2020 02:00:16

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:08', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8f85e070-5a78-4121-a5db-10dcba0005c2' User entered 'No (N)'	System	18 Aug 2020 02:00:16
	System	18 Aug 2020 02:00:16

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:10', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8f85e070-5a78-4121-a5db-10dcba0005c2'	System	18 Aug 2020 02:00:16
User entered 'None (1)'	System	18 Aug 2020 02:00:16

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:12', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8f85e070-5a78-4121-a5db-10dcba0005c2' User entered '17 Aug 2020 21:00'	System	18 Aug 2020 02:00:16
	System	18 Aug 2020 02:00:16

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 6'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:45', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fddacfe7-c6ff-4dfa-9e71-de8e0b0d246a'	System	19 Aug 2020 00:10:56
User entered 'None (1)'	System	19 Aug 2020 00:10:56

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:48', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fddacfe7-c6ff-4dfa-9e71-de8e0b0d246a'	System	19 Aug 2020 00:10:56
User entered 'No (N)'	System	19 Aug 2020 00:10:56

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fddacfe7-c6ff-4dfa-9e71-de8e0b0d246a'	System	19 Aug 2020 00:10:56
User entered 'No (N)'	System	19 Aug 2020 00:10:56

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:52', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fddacfe7-c6ff-4dfa-9e71-de8e0b0d246a'	System	19 Aug 2020 00:10:56
User entered 'None (1)'	System	19 Aug 2020 00:10:56

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:10:54', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fddacfe7-c6ff-4dfa-9e71-de8e0b0d246a'	System	19 Aug 2020 00:10:56
User entered '18 Aug 2020 19:10'	System	19 Aug 2020 00:10:56

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 7'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:48:53', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '894bd8aa-63e9-4c1d-954d-bbab2883b3af' User entered 'None (1)'	System	19 Aug 2020 21:49:04
	System	19 Aug 2020 21:49:04

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:48:56', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '894bd8aa-63e9-4c1d-954d-bbab2883b3af' User entered 'No (N)'	System	19 Aug 2020 21:49:04
	System	19 Aug 2020 21:49:04

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:48:57', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '894bd8aa-63e9-4c1d-954d-bbab2883b3af' User entered 'No (N)'	System	19 Aug 2020 21:49:04
	System	19 Aug 2020 21:49:04

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:48:59', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '894bd8aa-63e9-4c1d-954d-bbab2883b3af' User entered 'None (1)'	System	19 Aug 2020 21:49:04
	System	19 Aug 2020 21:49:04

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:01', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '894bd8aa-63e9-4c1d-954d-bbab2883b3af' User entered '19 Aug 2020 16:49'	System	19 Aug 2020 21:49:04
	System	19 Aug 2020 21:49:04

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:13', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '05fc82e2-ef6c-4400-9e4c-1164dc18a8a0' User entered 'None (0)'	System	13 Aug 2020 23:19:01
	System	13 Aug 2020 23:19:01

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:18', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '05fc82e2-ef6c-4400-9e4c-1164dc18a8a0' User entered 'None (0)'	System	13 Aug 2020 23:19:01
	System	13 Aug 2020 23:19:01

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:22', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '05fc82e2-ef6c-4400-9e4c-1164dc18a8a0' User entered 'None (0)'	System	13 Aug 2020 23:19:01
	System	13 Aug 2020 23:19:01

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '05fc82e2-ef6c-4400-9e4c-1164dc18a8a0' User entered 'None (0)'	System	13 Aug 2020 23:19:01
	System	13 Aug 2020 23:19:01

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:33', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '05fc82e2-ef6c-4400-9e4c-1164dc18a8a0' User entered 'None (0)'	System	13 Aug 2020 23:19:01
	System	13 Aug 2020 23:19:01

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:35', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '05fc82e2-ef6c-4400-9e4c-1164dc18a8a0' User entered 'None (0)'	System	13 Aug 2020 23:19:01
	System	13 Aug 2020 23:19:01

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:55', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '05fc82e2-ef6c-4400-9e4c-1164dc18a8a0'	System	13 Aug 2020 23:19:01
User entered 'No (N)'	System	13 Aug 2020 23:19:01

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T18:18:58', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '05fc82e2-ef6c-4400-9e4c-1164dc18a8a0'	System	13 Aug 2020 23:19:01
User entered '13 Aug 2020 18:18'	System	13 Aug 2020 23:19:01

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 17:47'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 20:17'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 1, after vaccination (at home)'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:26', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '83c20f61-89ef-4cc0-91f7-2cb5f41202e1' User entered 'None (0)'	System	14 Aug 2020 02:55:45
	System	14 Aug 2020 02:55:45

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '83c20f61-89ef-4cc0-91f7-2cb5f41202e1' User entered 'None (0)'	System	14 Aug 2020 02:55:45
	System	14 Aug 2020 02:55:45

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:31', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '83c20f61-89ef-4cc0-91f7-2cb5f41202e1' User entered 'None (0)'	System	14 Aug 2020 02:55:45
	System	14 Aug 2020 02:55:45

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:34', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '83c20f61-89ef-4cc0-91f7-2cb5f41202e1' User entered 'None (0)'	System	14 Aug 2020 02:55:45
	System	14 Aug 2020 02:55:45

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:36', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '83c20f61-89ef-4cc0-91f7-2cb5f41202e1' User entered 'None (0)'	System	14 Aug 2020 02:55:45
	System	14 Aug 2020 02:55:45

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:37', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '83c20f61-89ef-4cc0-91f7-2cb5f41202e1' User entered 'None (0)'	System	14 Aug 2020 02:55:45
	System	14 Aug 2020 02:55:45

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:40', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '83c20f61-89ef-4cc0-91f7-2cb5f41202e1' User entered 'No (N)'	System	14 Aug 2020 02:55:45
	System	14 Aug 2020 02:55:45

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-13T21:55:42', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '83c20f61-89ef-4cc0-91f7-2cb5f41202e1' User entered '13 Aug 2020 21:55'	System	14 Aug 2020 02:55:45
	System	14 Aug 2020 02:55:45

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Aug 2020 21:12'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 2'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:42', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '68146623-d169-4549-8a28-5995dc627752'	System	15 Aug 2020 02:14:04
User entered 'None (0)'	System	15 Aug 2020 02:14:04

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:46', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '68146623-d169-4549-8a28-5995dc627752'	System	15 Aug 2020 02:14:04
User entered 'None (0)'	System	15 Aug 2020 02:14:04

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '68146623-d169-4549-8a28-5995dc627752' User entered 'None (0)'	System	15 Aug 2020 02:14:04
	System	15 Aug 2020 02:14:04

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:52', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '68146623-d169-4549-8a28-5995dc627752' User entered 'None (0)'	System	15 Aug 2020 02:14:04
	System	15 Aug 2020 02:14:04

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:55', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '68146623-d169-4549-8a28-5995dc627752' User entered 'None (0)'	System	15 Aug 2020 02:14:04
	System	15 Aug 2020 02:14:04

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:13:57', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '68146623-d169-4549-8a28-5995dc627752'	System	15 Aug 2020 02:14:04
User entered 'None (0)'	System	15 Aug 2020 02:14:04

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:14:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '68146623-d169-4549-8a28-5995dc627752'	System	15 Aug 2020 02:14:04
User entered 'No (N)'	System	15 Aug 2020 02:14:04

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-14T21:14:02', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '68146623-d169-4549-8a28-5995dc627752'	System	15 Aug 2020 02:14:04
User entered '14 Aug 2020 21:14'	System	15 Aug 2020 02:14:04

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 3'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:35', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '80d75ef9-eb95-4e3b-ad00-8695b0e6f86d' User entered 'None (0)'	System	16 Aug 2020 10:58:54
	System	16 Aug 2020 10:58:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:38', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '80d75ef9-eb95-4e3b-ad00-8695b0e6f86d' User entered 'None (0)'	System	16 Aug 2020 10:58:54
	System	16 Aug 2020 10:58:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:41', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '80d75ef9-eb95-4e3b-ad00-8695b0e6f86d' User entered 'None (0)'	System	16 Aug 2020 10:58:54
	System	16 Aug 2020 10:58:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:43', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '80d75ef9-eb95-4e3b-ad00-8695b0e6f86d' User entered 'None (0)'	System	16 Aug 2020 10:58:54
	System	16 Aug 2020 10:58:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:46', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '80d75ef9-eb95-4e3b-ad00-8695b0e6f86d' User entered 'None (0)'	System	16 Aug 2020 10:58:54
	System	16 Aug 2020 10:58:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:48', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '80d75ef9-eb95-4e3b-ad00-8695b0e6f86d' User entered 'None (0)'	System	16 Aug 2020 10:58:54
	System	16 Aug 2020 10:58:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:51', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '80d75ef9-eb95-4e3b-ad00-8695b0e6f86d' User entered 'No (N)'	System	16 Aug 2020 10:58:54
	System	16 Aug 2020 10:58:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T05:58:53', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '80d75ef9-eb95-4e3b-ad00-8695b0e6f86d' User entered '16 Aug 2020 05:58'	System	16 Aug 2020 10:58:54
	System	16 Aug 2020 10:58:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 4'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:02:51', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '28cabdaa-2f1d-4b11-aebb-f5fbae8c5fdc' User entered 'None (0)'	System	16 Aug 2020 22:03:06
	System	16 Aug 2020 22:03:06

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:02:52', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '28cabdaa-2f1d-4b11-aebb-f5fbae8c5fdc' User entered 'None (0)'	System	16 Aug 2020 22:03:06
	System	16 Aug 2020 22:03:06

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:02:54', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '28cabdaa-2f1d-4b11-aebb-f5fbae8c5fdc' User entered 'None (0)'	System	16 Aug 2020 22:03:06
	System	16 Aug 2020 22:03:06

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:02:56', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '28cabdaa-2f1d-4b11-aebb-f5fbae8c5fdc' User entered 'None (0)'	System	16 Aug 2020 22:03:06
	System	16 Aug 2020 22:03:06

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:02:57', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '28cabdaa-2f1d-4b11-aebb-f5fbae8c5fdc' User entered 'None (0)'	System	16 Aug 2020 22:03:06
	System	16 Aug 2020 22:03:06

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '28cabdaa-2f1d-4b11-aebb-f5fbae8c5fdc' User entered 'None (0)'	System	16 Aug 2020 22:03:06
	System	16 Aug 2020 22:03:06

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:02', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '28cabdaa-2f1d-4b11-aebb-f5fbae8c5fdc'	System	16 Aug 2020 22:03:06
User entered 'No (N)'	System	16 Aug 2020 22:03:06

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-16T17:03:04', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '28cabdaa-2f1d-4b11-aebb-f5fbae8c5fdc' User entered '16 Aug 2020 17:03'	System	16 Aug 2020 22:03:06
	System	16 Aug 2020 22:03:06

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 5'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:18', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e30f2a63-3c1f-4765-ac6e-4bc1d6f9bce9' User entered 'None (0)'	System	18 Aug 2020 02:00:36
	System	18 Aug 2020 02:00:36

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:21', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e30f2a63-3c1f-4765-ac6e-4bc1d6f9bce9' User entered 'None (0)'	System	18 Aug 2020 02:00:36
	System	18 Aug 2020 02:00:36

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:22', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e30f2a63-3c1f-4765-ac6e-4bc1d6f9bce9' User entered 'None (0)'	System	18 Aug 2020 02:00:36
	System	18 Aug 2020 02:00:36

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:24', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e30f2a63-3c1f-4765-ac6e-4bc1d6f9bce9' User entered 'None (0)'	System	18 Aug 2020 02:00:36
	System	18 Aug 2020 02:00:36

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:26', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e30f2a63-3c1f-4765-ac6e-4bc1d6f9bce9' User entered 'None (0)'	System	18 Aug 2020 02:00:36
	System	18 Aug 2020 02:00:36

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:27', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e30f2a63-3c1f-4765-ac6e-4bc1d6f9bce9' User entered 'None (0)'	System	18 Aug 2020 02:00:36
	System	18 Aug 2020 02:00:36

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:30', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e30f2a63-3c1f-4765-ac6e-4bc1d6f9bce9' User entered 'No (N)'	System	18 Aug 2020 02:00:36
	System	18 Aug 2020 02:00:36

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-17T21:00:32', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e30f2a63-3c1f-4765-ac6e-4bc1d6f9bce9' User entered '17 Aug 2020 21:00'	System	18 Aug 2020 02:00:36
	System	18 Aug 2020 02:00:36

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 6'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:11:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '217131e6-e155-4a09-83be-93688f11c8df' User entered 'None (0)'	System	19 Aug 2020 00:11:16
	System	19 Aug 2020 00:11:16

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:11:02', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '217131e6-e155-4a09-83be-93688f11c8df' User entered 'None (0)'	System	19 Aug 2020 00:11:16
	System	19 Aug 2020 00:11:16

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:11:04', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '217131e6-e155-4a09-83be-93688f11c8df' User entered 'None (0)'	System	19 Aug 2020 00:11:16
	System	19 Aug 2020 00:11:16

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:11:05', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '217131e6-e155-4a09-83be-93688f11c8df' User entered 'None (0)'	System	19 Aug 2020 00:11:16
	System	19 Aug 2020 00:11:16

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:11:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '217131e6-e155-4a09-83be-93688f11c8df' User entered 'None (0)'	System	19 Aug 2020 00:11:16
	System	19 Aug 2020 00:11:16

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:11:08', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '217131e6-e155-4a09-83be-93688f11c8df' User entered 'None (0)'	System	19 Aug 2020 00:11:16
	System	19 Aug 2020 00:11:16

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:11:11', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '217131e6-e155-4a09-83be-93688f11c8df' User entered 'No (N)'	System	19 Aug 2020 00:11:16
	System	19 Aug 2020 00:11:16

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-18T19:11:14', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '217131e6-e155-4a09-83be-93688f11c8df' User entered '18 Aug 2020 19:11'	System	19 Aug 2020 00:11:16
	System	19 Aug 2020 00:11:16

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 7'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:05', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'b1556622-521f-4df2-8308-02537090dbe7' User entered 'None (0)'	System	19 Aug 2020 21:49:20
	System	19 Aug 2020 21:49:20

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:06', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'b1556622-521f-4df2-8308-02537090dbe7' User entered 'None (0)'	System	19 Aug 2020 21:49:20
	System	19 Aug 2020 21:49:20

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'b1556622-521f-4df2-8308-02537090dbe7' User entered 'None (0)'	System	19 Aug 2020 21:49:20
	System	19 Aug 2020 21:49:20

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:09', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'b1556622-521f-4df2-8308-02537090dbe7' User entered 'None (0)'	System	19 Aug 2020 21:49:20
	System	19 Aug 2020 21:49:20

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:10', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'b1556622-521f-4df2-8308-02537090dbe7' User entered 'None (0)'	System	19 Aug 2020 21:49:20
	System	19 Aug 2020 21:49:20

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:11', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'b1556622-521f-4df2-8308-02537090dbe7' User entered 'None (0)'	System	19 Aug 2020 21:49:20
	System	19 Aug 2020 21:49:20

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:13', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'b1556622-521f-4df2-8308-02537090dbe7' User entered 'No (N)'	System	19 Aug 2020 21:49:20
	System	19 Aug 2020 21:49:20

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-08-19T16:49:15', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'b1556622-521f-4df2-8308-02537090dbe7' User entered '19 Aug 2020 16:49'	System	19 Aug 2020 21:49:20
	System	19 Aug 2020 21:49:20

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Aug 2020 12:00'	System	13 Aug 2020 22:50:54

US3292173

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '20 Aug 2020 11:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	21 Aug 2020 15:50:20

US3292173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '21 Aug 2020'	(b) (4) Kristy Trevino (b) (4) (b) (4)	21 Aug 2020 15:50:20

US3292173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	21 Aug 2020 15:50:20

US3292173

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	21 Aug 2020 15:50:20

US3292173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Dawn Killian (b) (4)	25 Aug 2020 02:09:39

US3292173

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'l'	System	25 Aug 2020 02:09:39

US3292173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	27 Aug 2020 19:15:41

US3292173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '27 Aug 2020'	(b) (4) Kristy Trevino (b) (4)	27 Aug 2020 19:15:41

US3292173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	27 Aug 2020 19:15:41

US3292173

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	27 Aug 2020 19:15:41

US3292173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	27 Aug 2020 19:16:27

US3292173

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User entered 'l'	System	27 Aug 2020 19:16:27

US3292173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 15:34:47

US3292173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '3 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 15:34:47

US3292173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 15:34:47

US3292173

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 15:34:47

US3292173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
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	03 Sep 2020 15:35:21
User entered 'Yes (Y)' reason for change: Data Entry Error	Kristy Trevino (b) (4)	03 Sep 2020 15:35:21
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	03 Sep 2020 15:35:11
	Kristy Trevino (b) (4)	03 Sep 2020 15:35:11
	(b) (4)	

US3292173

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User entered 'l'	System	03 Sep 2020 15:35:21
User entered empty.	System	03 Sep 2020 15:35:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:46:36

US3292173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:46:36

US3292173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[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 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:46:36

US3292173

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'VISIT2'	System	12 Sep 2020 17:46:36

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '10:32'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '12 Sep 2020 10:32'	System	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '36.2' C	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '71'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'bpm'	System	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'breaths/min'	System	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '125'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '85'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	12 Sep 2020 17:47:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12:06'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '12 Sep 2020 12:06'	System	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '36.7' C	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '61'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'bpm'	System	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'breaths/min'	System	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '123'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '87'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	12 Sep 2020 17:48:12

US3292173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:48:22

US3292173

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:48:22

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

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 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'MRNA-1273 OR PLACEBO'	System	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12 Sep 2020'	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '11:36'	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '12 Sep 2020 11:36'	System	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Right Arm (RIGHT ARM)'	(b) (4) Nathan Cortez (b) (4)	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'ONCE'	System	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'INTRAMUSCULAR'	System	12 Sep 2020 16:40:56

US3292173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:44

US3292173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:44

US3292173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '10:42'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:48:44

US3292173

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '12 Sep 2020 10:42'	System	12 Sep 2020 17:48:44

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12 Sep 2020'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '10:55'	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:27:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '12 Sep 2020 10:55'	System	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:36

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:27:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered empty.	System	12 Sep 2020 17:49:00

US3292173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	12 Sep 2020 17:49:11

US3292173

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'I'	System	12 Sep 2020 17:49:11

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:10:48', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'eb1c50df-a463-4b24-b889-e48a23a140f4' User entered 'Yes (Y)'	System	12 Sep 2020 17:11:11
	System	12 Sep 2020 17:11:11

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:01', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'eb1c50df-a463-4b24-b889-e48a23a140f4' User entered '98.0'	System	12 Sep 2020 17:11:11
	System	12 Sep 2020 17:11:11

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:05', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'eb1c50df-a463-4b24-b889-e48a23a140f4'	System	12 Sep 2020 17:11:11
User entered 'No (N)'	System	12 Sep 2020 17:11:11

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:10', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'eb1c50df-a463-4b24-b889-e48a23a140f4' User entered '12 Sep 2020 12:11'	System	12 Sep 2020 17:11:11
	System	12 Sep 2020 17:11:11

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 11:56'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 14:26'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:38:28', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fd36bc2e-797b-4fe4-8a2b-b57dca78d46a' User entered 'Yes (Y)'	System	13 Sep 2020 03:41:01
	System	13 Sep 2020 03:41:01

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:40:51', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fd36bc2e-797b-4fe4-8a2b-b57dca78d46a' User entered '97.0'	System	13 Sep 2020 03:41:01
	System	13 Sep 2020 03:41:01

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:40:55', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fd36bc2e-797b-4fe4-8a2b-b57dca78d46a'	System	13 Sep 2020 03:41:01
User entered 'No (N)'	System	13 Sep 2020 03:41:01

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:40:58', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fd36bc2e-797b-4fe4-8a2b-b57dca78d46a' User entered '12 Sep 2020 22:40'	System	13 Sep 2020 03:41:01
	System	13 Sep 2020 03:41:01

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 15:21'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 2'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:17', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0b9fb88e-6b98-4a9c-9aca-dd992806efdf' User entered 'Yes (Y)'	System	13 Sep 2020 22:24:30
	System	13 Sep 2020 22:24:30

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:22', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0b9fb88e-6b98-4a9c-9aca-dd992806efdf' User entered '97.8'	System	13 Sep 2020 22:24:30
	System	13 Sep 2020 22:24:30

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:25', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0b9fb88e-6b98-4a9c-9aca-dd992806efdf'	System	13 Sep 2020 22:24:30
User entered 'No (N)'	System	13 Sep 2020 22:24:30

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:28', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0b9fb88e-6b98-4a9c-9aca-dd992806efdf' User entered '13 Sep 2020 17:24'	System	13 Sep 2020 22:24:30
	System	13 Sep 2020 22:24:30

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 3'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:06', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd4b2e878-d96b-4e3b-9637-b4867f1ebc21' User entered 'Yes (Y)'	System	15 Sep 2020 11:16:22
	System	15 Sep 2020 11:16:22

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:14', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd4b2e878-d96b-4e3b-9637-b4867f1ebc21' User entered '97.2'	System	15 Sep 2020 11:16:22
	System	15 Sep 2020 11:16:22

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:18', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd4b2e878-d96b-4e3b-9637-b4867f1ebc21' User entered 'No (N)'	System	15 Sep 2020 11:16:22
	System	15 Sep 2020 11:16:22

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:21', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd4b2e878-d96b-4e3b-9637-b4867f1ebc21' User entered '15 Sep 2020 06:16'	System	15 Sep 2020 11:16:22
	System	15 Sep 2020 11:16:22

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 4'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:15', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ee431266-8741-4b27-a53d-518dc1ad794e' User entered 'Yes (Y)'	System	16 Sep 2020 00:30:27
	System	16 Sep 2020 00:30:27

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:19', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ee431266-8741-4b27-a53d-518dc1ad794e' User entered '98.0'	System	16 Sep 2020 00:30:27
	System	16 Sep 2020 00:30:27

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:22', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ee431266-8741-4b27-a53d-518dc1ad794e' User entered 'No (N)'	System	16 Sep 2020 00:30:27
	System	16 Sep 2020 00:30:27

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:25', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ee431266-8741-4b27-a53d-518dc1ad794e' User entered '15 Sep 2020 19:30'	System	16 Sep 2020 00:30:27
	System	16 Sep 2020 00:30:27

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 5'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:49', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8a628eb2-006c-45a2-859b-c1c03b201baa' User entered 'Yes (Y)'	System	17 Sep 2020 12:03:21
	System	17 Sep 2020 12:03:21

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:03:02', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8a628eb2-006c-45a2-859b-c1c03b201baa' User entered '96.9'	System	17 Sep 2020 12:03:21
	System	17 Sep 2020 12:03:21

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:03:05', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8a628eb2-006c-45a2-859b-c1c03b201baa'	System	17 Sep 2020 12:03:21
User entered 'No (N)'	System	17 Sep 2020 12:03:21

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:03:19', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '8a628eb2-006c-45a2-859b-c1c03b201baa' User entered '17 Sep 2020 07:03'	System	17 Sep 2020 12:03:21
	System	17 Sep 2020 12:03:21

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 6'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:34', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '440bef19-6a27-4526-b207-67b67b369636' User entered 'Yes (Y)'	System	17 Sep 2020 21:16:07
	System	17 Sep 2020 21:16:07

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:58', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '440bef19-6a27-4526-b207-67b67b369636' User entered '97.0'	System	17 Sep 2020 21:16:07
	System	17 Sep 2020 21:16:07

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:16:01', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '440bef19-6a27-4526-b207-67b67b369636'	System	17 Sep 2020 21:16:07
User entered 'No (N)'	System	17 Sep 2020 21:16:07

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:16:03', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '440bef19-6a27-4526-b207-67b67b369636' User entered '17 Sep 2020 16:16'	System	17 Sep 2020 21:16:07
	System	17 Sep 2020 21:16:07

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 7'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:32', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fb5865f8-b0e7-4daf-9e03-aaacc0c62298'	System	18 Sep 2020 20:02:54
User entered 'Yes (Y)'	System	18 Sep 2020 20:02:54

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:40', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fb5865f8-b0e7-4daf-9e03-aaacc0c62298' User entered '97.4'	System	18 Sep 2020 20:02:54
	System	18 Sep 2020 20:02:54

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:44', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fb5865f8-b0e7-4daf-9e03-aaacc0c62298'	System	18 Sep 2020 20:02:54
User entered 'No (N)'	System	18 Sep 2020 20:02:54

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:47', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'fb5865f8-b0e7-4daf-9e03-aaacc0c62298'	System	18 Sep 2020 20:02:54
User entered '18 Sep 2020 15:02'	System	18 Sep 2020 20:02:54

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:16', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4e727c49-ac15-493f-b208-bbea79aced1a' User entered 'None (1)'	System	12 Sep 2020 17:11:43
	System	12 Sep 2020 17:11:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:23', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4e727c49-ac15-493f-b208-bbea79aced1a' User entered 'No (N)'	System	12 Sep 2020 17:11:43
	System	12 Sep 2020 17:11:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4e727c49-ac15-493f-b208-bbea79aced1a' User entered 'No (N)'	System	12 Sep 2020 17:11:43
	System	12 Sep 2020 17:11:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:38', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4e727c49-ac15-493f-b208-bbea79aced1a' User entered 'None (1)'	System	12 Sep 2020 17:11:43
	System	12 Sep 2020 17:11:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:41', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4e727c49-ac15-493f-b208-bbea79aced1a' User entered '12 Sep 2020 12:11'	System	12 Sep 2020 17:11:43
	System	12 Sep 2020 17:11:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 11:56'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 14:26'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:43', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ac604d5e-7f10-4496-a46b-96cffc61e408'	System	13 Sep 2020 03:38:03
User entered 'None (1)'	System	13 Sep 2020 03:38:03

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ac604d5e-7f10-4496-a46b-96cffc61e408'	System	13 Sep 2020 03:38:03
User entered 'No (N)'	System	13 Sep 2020 03:38:03

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:53', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ac604d5e-7f10-4496-a46b-96cffc61e408'	System	13 Sep 2020 03:38:03
User entered 'No (N)'	System	13 Sep 2020 03:38:03

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:55', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ac604d5e-7f10-4496-a46b-96cffc61e408'	System	13 Sep 2020 03:38:03
User entered 'None (1)'	System	13 Sep 2020 03:38:03

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:58', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ac604d5e-7f10-4496-a46b-96cffc61e408'	System	13 Sep 2020 03:38:03
User entered '12 Sep 2020 22:37'	System	13 Sep 2020 03:38:03

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 15:21'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 2'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:32', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3d275335-4225-4957-9b58-e3859c5dc820'	System	13 Sep 2020 22:24:43
User entered 'None (1)'	System	13 Sep 2020 22:24:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:35', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3d275335-4225-4957-9b58-e3859c5dc820'	System	13 Sep 2020 22:24:43
User entered 'No (N)'	System	13 Sep 2020 22:24:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:37', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3d275335-4225-4957-9b58-e3859c5dc820'	System	13 Sep 2020 22:24:43
User entered 'No (N)'	System	13 Sep 2020 22:24:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:39', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3d275335-4225-4957-9b58-e3859c5dc820'	System	13 Sep 2020 22:24:43
User entered 'None (1)'	System	13 Sep 2020 22:24:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:41', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3d275335-4225-4957-9b58-e3859c5dc820'	System	13 Sep 2020 22:24:43
User entered '13 Sep 2020 17:24'	System	13 Sep 2020 22:24:43

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 3'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:25', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0f8b37a7-fb96-4d67-b381-840797d12de0' User entered 'None (1)'	System	15 Sep 2020 11:16:36
	System	15 Sep 2020 11:16:36

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:28', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0f8b37a7-fb96-4d67-b381-840797d12de0' User entered 'No (N)'	System	15 Sep 2020 11:16:36
	System	15 Sep 2020 11:16:36

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0f8b37a7-fb96-4d67-b381-840797d12de0' User entered 'No (N)'	System	15 Sep 2020 11:16:36
	System	15 Sep 2020 11:16:36

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:31', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0f8b37a7-fb96-4d67-b381-840797d12de0' User entered 'None (1)'	System	15 Sep 2020 11:16:36
	System	15 Sep 2020 11:16:36

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:33', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '0f8b37a7-fb96-4d67-b381-840797d12de0' User entered '15 Sep 2020 06:16'	System	15 Sep 2020 11:16:36
	System	15 Sep 2020 11:16:36

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 4'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:34', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6754c0fa-322b-488e-92d6-2d9d50dd53da' User entered 'None (1)'	System	16 Sep 2020 00:30:45
	System	16 Sep 2020 00:30:45

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:37', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6754c0fa-322b-488e-92d6-2d9d50dd53da' User entered 'No (N)'	System	16 Sep 2020 00:30:45
	System	16 Sep 2020 00:30:45

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:38', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6754c0fa-322b-488e-92d6-2d9d50dd53da' User entered 'No (N)'	System	16 Sep 2020 00:30:45
	System	16 Sep 2020 00:30:45

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:40', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6754c0fa-322b-488e-92d6-2d9d50dd53da' User entered 'None (1)'	System	16 Sep 2020 00:30:45
	System	16 Sep 2020 00:30:45

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:43', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6754c0fa-322b-488e-92d6-2d9d50dd53da' User entered '15 Sep 2020 19:30'	System	16 Sep 2020 00:30:45
	System	16 Sep 2020 00:30:45

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 5'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:33', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2bac0de5-db76-4910-8e64-426153632093'	System	17 Sep 2020 12:01:46
User entered 'None (1)'	System	17 Sep 2020 12:01:46

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:37', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2bac0de5-db76-4910-8e64-426153632093'	System	17 Sep 2020 12:01:46
User entered 'No (N)'	System	17 Sep 2020 12:01:46

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:38', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2bac0de5-db76-4910-8e64-426153632093'	System	17 Sep 2020 12:01:46
User entered 'No (N)'	System	17 Sep 2020 12:01:46

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:40', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2bac0de5-db76-4910-8e64-426153632093'	System	17 Sep 2020 12:01:46
User entered 'None (1)'	System	17 Sep 2020 12:01:46

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:43', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2bac0de5-db76-4910-8e64-426153632093' User entered '17 Sep 2020 07:01'	System	17 Sep 2020 12:01:46
	System	17 Sep 2020 12:01:46

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 6'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:22', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6caf3192-9a79-497f-9c45-11fe5d99a106'	System	17 Sep 2020 21:15:34
User entered 'None (1)'	System	17 Sep 2020 21:15:34

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:24', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6caf3192-9a79-497f-9c45-11fe5d99a106'	System	17 Sep 2020 21:15:34
User entered 'No (N)'	System	17 Sep 2020 21:15:34

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:25', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6caf3192-9a79-497f-9c45-11fe5d99a106'	System	17 Sep 2020 21:15:34
User entered 'No (N)'	System	17 Sep 2020 21:15:34

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:26', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6caf3192-9a79-497f-9c45-11fe5d99a106'	System	17 Sep 2020 21:15:34
User entered 'None (1)'	System	17 Sep 2020 21:15:34

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6caf3192-9a79-497f-9c45-11fe5d99a106'	System	17 Sep 2020 21:15:34
User entered '17 Sep 2020 16:15'	System	17 Sep 2020 21:15:34

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 7'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:03', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'de198f11-41a5-4902-a3a8-25d5db4fa796'	System	18 Sep 2020 20:02:15
User entered 'None (1)'	System	18 Sep 2020 20:02:15

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:06', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'de198f11-41a5-4902-a3a8-25d5db4fa796'	System	18 Sep 2020 20:02:15
User entered 'No (N)'	System	18 Sep 2020 20:02:15

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'de198f11-41a5-4902-a3a8-25d5db4fa796'	System	18 Sep 2020 20:02:15
User entered 'No (N)'	System	18 Sep 2020 20:02:15

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:10', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'de198f11-41a5-4902-a3a8-25d5db4fa796'	System	18 Sep 2020 20:02:15
User entered 'None (1)'	System	18 Sep 2020 20:02:15

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:02:13', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'de198f11-41a5-4902-a3a8-25d5db4fa796' User entered '18 Sep 2020 15:02'	System	18 Sep 2020 20:02:15
	System	18 Sep 2020 20:02:15

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:44', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '59d5e6eb-d0f4-4779-b879-1d81e450a9d5' User entered 'None (0)'	System	12 Sep 2020 17:12:04
	System	12 Sep 2020 17:12:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:46', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '59d5e6eb-d0f4-4779-b879-1d81e450a9d5' User entered 'None (0)'	System	12 Sep 2020 17:12:04
	System	12 Sep 2020 17:12:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:49', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '59d5e6eb-d0f4-4779-b879-1d81e450a9d5' User entered 'None (0)'	System	12 Sep 2020 17:12:04
	System	12 Sep 2020 17:12:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '59d5e6eb-d0f4-4779-b879-1d81e450a9d5' User entered 'None (0)'	System	12 Sep 2020 17:12:04
	System	12 Sep 2020 17:12:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:53', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '59d5e6eb-d0f4-4779-b879-1d81e450a9d5' User entered 'None (0)'	System	12 Sep 2020 17:12:04
	System	12 Sep 2020 17:12:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:55', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '59d5e6eb-d0f4-4779-b879-1d81e450a9d5' User entered 'None (0)'	System	12 Sep 2020 17:12:04
	System	12 Sep 2020 17:12:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:11:59', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '59d5e6eb-d0f4-4779-b879-1d81e450a9d5' User entered 'No (N)'	System	12 Sep 2020 17:12:04
	System	12 Sep 2020 17:12:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T12:12:01', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '59d5e6eb-d0f4-4779-b879-1d81e450a9d5' User entered '12 Sep 2020 12:12'	System	12 Sep 2020 17:12:04
	System	12 Sep 2020 17:12:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 11:56'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 14:26'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 1, after vaccination (at home)'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:27', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4d8c39d3-1afb-48da-a9b5-1425d8990b2d' User entered 'None (0)'	System	13 Sep 2020 03:37:42
	System	13 Sep 2020 03:37:42

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:30', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4d8c39d3-1afb-48da-a9b5-1425d8990b2d' User entered 'None (0)'	System	13 Sep 2020 03:37:42
	System	13 Sep 2020 03:37:42

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:31', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4d8c39d3-1afb-48da-a9b5-1425d8990b2d' User entered 'None (0)'	System	13 Sep 2020 03:37:42
	System	13 Sep 2020 03:37:42

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:32', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4d8c39d3-1afb-48da-a9b5-1425d8990b2d' User entered 'None (0)'	System	13 Sep 2020 03:37:42
	System	13 Sep 2020 03:37:42

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:34', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4d8c39d3-1afb-48da-a9b5-1425d8990b2d' User entered 'None (0)'	System	13 Sep 2020 03:37:42
	System	13 Sep 2020 03:37:42

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:35', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4d8c39d3-1afb-48da-a9b5-1425d8990b2d' User entered 'None (0)'	System	13 Sep 2020 03:37:42
	System	13 Sep 2020 03:37:42

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:37', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4d8c39d3-1afb-48da-a9b5-1425d8990b2d' User entered 'No (N)'	System	13 Sep 2020 03:37:42
	System	13 Sep 2020 03:37:42

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-12T22:37:39', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4d8c39d3-1afb-48da-a9b5-1425d8990b2d' User entered '12 Sep 2020 22:37'	System	13 Sep 2020 03:37:42
	System	13 Sep 2020 03:37:42

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '12 Sep 2020 15:21'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 2'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:45', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '5872a7f7-dd2f-4ad4-88f4-ee1edf94a2a0' User entered 'None (0)'	System	13 Sep 2020 22:24:57
	System	13 Sep 2020 22:24:57

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:46', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '5872a7f7-dd2f-4ad4-88f4-ee1edf94a2a0' User entered 'None (0)'	System	13 Sep 2020 22:24:57
	System	13 Sep 2020 22:24:57

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:47', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '5872a7f7-dd2f-4ad4-88f4-ee1edf94a2a0' User entered 'None (0)'	System	13 Sep 2020 22:24:57
	System	13 Sep 2020 22:24:57

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:49', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '5872a7f7-dd2f-4ad4-88f4-ee1edf94a2a0' User entered 'None (0)'	System	13 Sep 2020 22:24:57
	System	13 Sep 2020 22:24:57

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '5872a7f7-dd2f-4ad4-88f4-ee1edf94a2a0' User entered 'None (0)'	System	13 Sep 2020 22:24:57
	System	13 Sep 2020 22:24:57

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:51', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '5872a7f7-dd2f-4ad4-88f4-ee1edf94a2a0' User entered 'None (0)'	System	13 Sep 2020 22:24:57
	System	13 Sep 2020 22:24:57

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:53', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '5872a7f7-dd2f-4ad4-88f4-ee1edf94a2a0'	System	13 Sep 2020 22:24:57
User entered 'No (N)'	System	13 Sep 2020 22:24:57

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-13T17:24:56', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '5872a7f7-dd2f-4ad4-88f4-ee1edf94a2a0'	System	13 Sep 2020 22:24:57
User entered '13 Sep 2020 17:24'	System	13 Sep 2020 22:24:57

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '13 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 3'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:36', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '691d0101-377a-44db-a7e3-30e4a593f778' User entered 'None (0)'	System	15 Sep 2020 11:16:51
	System	15 Sep 2020 11:16:51

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:38', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '691d0101-377a-44db-a7e3-30e4a593f778' User entered 'None (0)'	System	15 Sep 2020 11:16:51
	System	15 Sep 2020 11:16:51

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:39', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '691d0101-377a-44db-a7e3-30e4a593f778' User entered 'None (0)'	System	15 Sep 2020 11:16:51
	System	15 Sep 2020 11:16:51

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:41', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '691d0101-377a-44db-a7e3-30e4a593f778' User entered 'None (0)'	System	15 Sep 2020 11:16:51
	System	15 Sep 2020 11:16:51

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:42', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '691d0101-377a-44db-a7e3-30e4a593f778' User entered 'None (0)'	System	15 Sep 2020 11:16:51
	System	15 Sep 2020 11:16:51

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:44', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '691d0101-377a-44db-a7e3-30e4a593f778' User entered 'None (0)'	System	15 Sep 2020 11:16:51
	System	15 Sep 2020 11:16:51

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:46', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '691d0101-377a-44db-a7e3-30e4a593f778' User entered 'No (N)'	System	15 Sep 2020 11:16:51
	System	15 Sep 2020 11:16:51

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T06:16:49', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '691d0101-377a-44db-a7e3-30e4a593f778'	System	15 Sep 2020 11:16:51
User entered '15 Sep 2020 06:16'	System	15 Sep 2020 11:16:51

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '14 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 4'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:46', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '01246f0a-f931-4444-9510-e17570c56d8a' User entered 'None (0)'	System	16 Sep 2020 00:31:04
	System	16 Sep 2020 00:31:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:47', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '01246f0a-f931-4444-9510-e17570c56d8a' User entered 'None (0)'	System	16 Sep 2020 00:31:04
	System	16 Sep 2020 00:31:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:48', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '01246f0a-f931-4444-9510-e17570c56d8a' User entered 'None (0)'	System	16 Sep 2020 00:31:04
	System	16 Sep 2020 00:31:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '01246f0a-f931-4444-9510-e17570c56d8a' User entered 'None (0)'	System	16 Sep 2020 00:31:04
	System	16 Sep 2020 00:31:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:51', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '01246f0a-f931-4444-9510-e17570c56d8a' User entered 'None (0)'	System	16 Sep 2020 00:31:04
	System	16 Sep 2020 00:31:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:52', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '01246f0a-f931-4444-9510-e17570c56d8a' User entered 'None (0)'	System	16 Sep 2020 00:31:04
	System	16 Sep 2020 00:31:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:30:55', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '01246f0a-f931-4444-9510-e17570c56d8a' User entered 'No (N)'	System	16 Sep 2020 00:31:04
	System	16 Sep 2020 00:31:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-15T19:31:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '01246f0a-f931-4444-9510-e17570c56d8a' User entered '15 Sep 2020 19:31'	System	16 Sep 2020 00:31:04
	System	16 Sep 2020 00:31:04

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '15 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 5'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:01', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7d0ba4fc-cdca-4f21-8a26-c23876243eca' User entered 'None (0)'	System	17 Sep 2020 12:01:32
	System	17 Sep 2020 12:01:32

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:02', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7d0ba4fc-cdca-4f21-8a26-c23876243eca' User entered 'None (0)'	System	17 Sep 2020 12:01:32
	System	17 Sep 2020 12:01:32

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:04', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7d0ba4fc-cdca-4f21-8a26-c23876243eca' User entered 'None (0)'	System	17 Sep 2020 12:01:32
	System	17 Sep 2020 12:01:32

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:05', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7d0ba4fc-cdca-4f21-8a26-c23876243eca' User entered 'None (0)'	System	17 Sep 2020 12:01:32
	System	17 Sep 2020 12:01:32

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7d0ba4fc-cdca-4f21-8a26-c23876243eca' User entered 'None (0)'	System	17 Sep 2020 12:01:32
	System	17 Sep 2020 12:01:32

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:08', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7d0ba4fc-cdca-4f21-8a26-c23876243eca' User entered 'None (0)'	System	17 Sep 2020 12:01:32
	System	17 Sep 2020 12:01:32

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:12', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7d0ba4fc-cdca-4f21-8a26-c23876243eca' User entered 'No (N)'	System	17 Sep 2020 12:01:32
	System	17 Sep 2020 12:01:32

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T07:01:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '7d0ba4fc-cdca-4f21-8a26-c23876243eca' User entered '17 Sep 2020 07:01'	System	17 Sep 2020 12:01:32
	System	17 Sep 2020 12:01:32

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '16 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 6'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:09', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4aa88136-8460-4664-b563-8070a5424a8f' User entered 'None (0)'	System	17 Sep 2020 21:15:22
	System	17 Sep 2020 21:15:22

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:10', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4aa88136-8460-4664-b563-8070a5424a8f' User entered 'None (0)'	System	17 Sep 2020 21:15:22
	System	17 Sep 2020 21:15:22

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:12', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4aa88136-8460-4664-b563-8070a5424a8f' User entered 'None (0)'	System	17 Sep 2020 21:15:22
	System	17 Sep 2020 21:15:22

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:13', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4aa88136-8460-4664-b563-8070a5424a8f' User entered 'None (0)'	System	17 Sep 2020 21:15:22
	System	17 Sep 2020 21:15:22

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:14', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4aa88136-8460-4664-b563-8070a5424a8f' User entered 'None (0)'	System	17 Sep 2020 21:15:22
	System	17 Sep 2020 21:15:22

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:15', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4aa88136-8460-4664-b563-8070a5424a8f' User entered 'None (0)'	System	17 Sep 2020 21:15:22
	System	17 Sep 2020 21:15:22

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:17', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4aa88136-8460-4664-b563-8070a5424a8f' User entered 'No (N)'	System	17 Sep 2020 21:15:22
	System	17 Sep 2020 21:15:22

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-17T16:15:19', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4aa88136-8460-4664-b563-8070a5424a8f' User entered '17 Sep 2020 16:15'	System	17 Sep 2020 21:15:22
	System	17 Sep 2020 21:15:22

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '17 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	12 Sep 2020 16:40:56
User entered 'Day 7'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:01:44', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2529293d-1312-440a-898d-665e8321d71f' User entered 'None (0)'	System	18 Sep 2020 20:02:03
	System	18 Sep 2020 20:02:03

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:01:47', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2529293d-1312-440a-898d-665e8321d71f' User entered 'None (0)'	System	18 Sep 2020 20:02:03
	System	18 Sep 2020 20:02:03

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:01:49', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2529293d-1312-440a-898d-665e8321d71f' User entered 'None (0)'	System	18 Sep 2020 20:02:03
	System	18 Sep 2020 20:02:03

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:01:50', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2529293d-1312-440a-898d-665e8321d71f' User entered 'None (0)'	System	18 Sep 2020 20:02:03
	System	18 Sep 2020 20:02:03

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:01:52', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2529293d-1312-440a-898d-665e8321d71f' User entered 'None (0)'	System	18 Sep 2020 20:02:03
	System	18 Sep 2020 20:02:03

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:01:54', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2529293d-1312-440a-898d-665e8321d71f' User entered 'None (0)'	System	18 Sep 2020 20:02:03
	System	18 Sep 2020 20:02:03

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:01:57', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2529293d-1312-440a-898d-665e8321d71f' User entered 'No (N)'	System	18 Sep 2020 20:02:03
	System	18 Sep 2020 20:02:03

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-09-18T15:01:59', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2529293d-1312-440a-898d-665e8321d71f' User entered '18 Sep 2020 15:01'	System	18 Sep 2020 20:02:03
	System	18 Sep 2020 20:02:03

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '18 Sep 2020 12:00'	System	12 Sep 2020 16:40:56

US3292173

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:27:36

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
User entered '19 Sep 2020 11:59'	System	12 Sep 2020 16:40:56

US3292173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 19:59:17

US3292173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
Query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	28 Sep 2020 20:00:22
User entered '21 Sep 2020' reason for change: Data Entry Error	Kristy Trevino (b) (4)	28 Sep 2020 20:00:22
User opened query 'Safety Call Day 36 'Date of Contact or Contact Attempt' is less than 7 days or greater than 10 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
User entered '28 Sep 2020'	System	28 Sep 2020 19:59:17
	Kristy Trevino (b) (4)	28 Sep 2020 19:59:17
	(b) (4)	

US3292173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4)	
	Kristy Trevino (b) (4)	28 Sep 2020 20:00:22
User entered 'Contact Made (CONTACT MADE)'	(b) (4)	
	Kristy Trevino (b) (4)	28 Sep 2020 19:59:17
	(b) (4)	

US3292173

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	(b) (4) System	28 Sep 2020 20:00:51
Please review and reconcile.' (Site from System).		
User entered 'One attempt was made, unsuccessful , visit not complete' reason for change: Data Entry Error	Kristy Trevino (b) (4)	28 Sep 2020 20:00:51
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	28 Sep 2020 20:00:22
Please review and reconcile.' (Site from System).		
User entered empty.	Kristy Trevino (b) (4)	28 Sep 2020 19:59:17

US3292173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:00:56

US3292173

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User entered 'l'	System	28 Sep 2020 20:00:56

US3292173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:01:10

US3292173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '28 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:01:10

US3292173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:01:10

US3292173

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	28 Sep 2020 20:01:10

US3292173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:01:19

US3292173

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:32
User entered 'l'	System	28 Sep 2020 20:01:19

US3292173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	05 Oct 2020 14:45:42

US3292173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '5 Oct 2020'	(b) (4) Kristy Trevino (b) (4)	05 Oct 2020 14:45:42

US3292173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Kristy Trevino (b) (4)	05 Oct 2020 14:45:42

US3292173

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Kristy Trevino (b) (4) (b) (4)	05 Oct 2020 14:45:42

US3292173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	05 Oct 2020 14:45:54

US3292173

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'l'	System	05 Oct 2020 14:45:54

US3292173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:16

US3292173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Oct 2020'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:16

US3292173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[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 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	13 Oct 2020 20:50:16

US3292173

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'VISIT3'	System	13 Oct 2020 20:50:16

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Oct 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13:27'	(b) (4) Gerardo Pena (b) (4) (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '13 Oct 2020 13:27'	System	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '36.3' C	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (Oral)'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '78'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'bpm'	System	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '16'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'breaths/min'	System	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '126'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '83'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'mmHg'	System	13 Oct 2020 20:50:44

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58

US3292173

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58

US3292173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:49

US3292173

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	13 Oct 2020 20:50:49

US3292173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:59

US3292173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13 Oct 2020'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:59

US3292173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '13:35'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:50:59

US3292173

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered '13 Oct 2020 13:35'	System	13 Oct 2020 20:50:59

US3292173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	13 Oct 2020 20:51:03

US3292173

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'I'	System	13 Oct 2020 20:51:03

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 64'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-13T06:14:44', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd037f091-bd4c-48d8-bc0e-47d90c535ff7'	System	13 Oct 2020 11:14:58
User entered 'No (N)'	System	13 Oct 2020 11:14:58

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-13T06:14:52', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd037f091-bd4c-48d8-bc0e-47d90c535ff7'	System	13 Oct 2020 11:14:58
User entered 'No (N)'	System	13 Oct 2020 11:14:58

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-13T06:14:56', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd037f091-bd4c-48d8-bc0e-47d90c535ff7' User entered '13 Oct 2020 06:14:56'	System	13 Oct 2020 11:14:58
	System	13 Oct 2020 11:14:58

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '13 Oct 2020 00:01'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '17 Oct 2020 23:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 71'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-22T12:01:36', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '313bf0dd-f7a4-44e7-9b73-007361044995'	System	22 Oct 2020 17:01:59
User entered 'No (N)'	System	22 Oct 2020 17:01:59

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-22T12:01:41', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '313bf0dd-f7a4-44e7-9b73-007361044995'	System	22 Oct 2020 17:01:59
User entered 'No (N)'	System	22 Oct 2020 17:01:59

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-22T12:01:44', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '313bf0dd-f7a4-44e7-9b73-007361044995' User entered '22 Oct 2020 12:01:44'	System	22 Oct 2020 17:01:59
	System	22 Oct 2020 17:01:59

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '20 Oct 2020 00:01'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '24 Oct 2020 23:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 78'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-27T09:04:24', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ac14db14-26eb-4ca9-b545-df2ce916ddd6'	System	27 Oct 2020 14:04:39
User entered 'No (N)'	System	27 Oct 2020 14:04:39

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-27T09:04:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ac14db14-26eb-4ca9-b545-df2ce916ddd6'	System	27 Oct 2020 14:04:39
User entered 'No (N)'	System	27 Oct 2020 14:04:39

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-10-27T09:04:34', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ac14db14-26eb-4ca9-b545-df2ce916ddd6' User entered '27 Oct 2020 09:04:34'	System	27 Oct 2020 14:04:39
	System	27 Oct 2020 14:04:39

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '27 Oct 2020 00:01'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '31 Oct 2020 23:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 92'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-11T14:20:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '15b16091-6107-4455-884c-405ce2974366'	System	11 Nov 2020 20:20:38
User entered 'No (N)'	System	11 Nov 2020 20:20:38

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-11T14:20:32', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '15b16091-6107-4455-884c-405ce2974366'	System	11 Nov 2020 20:20:38
User entered 'No (N)'	System	11 Nov 2020 20:20:38

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-11T14:20:36', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '15b16091-6107-4455-884c-405ce2974366'	System	11 Nov 2020 20:20:38
User entered '11 Nov 2020 14:20:36'	System	11 Nov 2020 20:20:38

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '10 Nov 2020 00:01'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '14 Nov 2020 23:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered 'Day 99'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-17T07:01:49', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '839e1357-cf32-440c-ad4a-3d2bdeec5a76'	System	17 Nov 2020 13:02:02
User entered 'No (N)'	System	17 Nov 2020 13:02:02

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-17T07:01:56', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '839e1357-cf32-440c-ad4a-3d2bdeec5a76'	System	17 Nov 2020 13:02:02
User entered 'No (N)'	System	17 Nov 2020 13:02:02

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-17T07:01:59', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '839e1357-cf32-440c-ad4a-3d2bdeec5a76' User entered '17 Nov 2020 07:01:59'	System	17 Nov 2020 13:02:02
	System	17 Nov 2020 13:02:02

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '17 Nov 2020 00:01'	System	13 Aug 2020 22:50:54

US3292173

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:01:09
Data entry locked.	System	13 Aug 2020 22:50:54
User entered '21 Nov 2020 23:59'	System	13 Aug 2020 22:50:54

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-23T18:02:45', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9e52779d-2cbf-4c5b-9860-3d83591f682c' User entered 'No (N)'	System	24 Nov 2020 00:03:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-23T18:02:47', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9e52779d-2cbf-4c5b-9860-3d83591f682c' User entered 'No (N)'	System	24 Nov 2020 00:03:10
	System	24 Nov 2020 00:03:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-23T18:02:51', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9e52779d-2cbf-4c5b-9860-3d83591f682c' User entered '23 Nov 2020 18:02:51'	System	24 Nov 2020 00:03:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-29T19:24:29', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '465f9fd0-0b74-4c81-b015-f9452b1fde4e' User entered 'No (N)'	System	30 Nov 2020 01:24:41

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-29T19:24:35', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '465f9fd0-0b74-4c81-b015-f9452b1fde4e' User entered 'No (N)'	System	30 Nov 2020 01:24:41

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-11-29T19:24:38', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '465f9fd0-0b74-4c81-b015-f9452b1fde4e' User entered '29 Nov 2020 19:24:38'	System	30 Nov 2020 01:24:41

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-05T14:00:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd17391a9-77d6-424a-a4fa-fc0498d79c0d' User entered 'No (N)'	System	05 Dec 2020 20:00:16
	System	05 Dec 2020 20:00:16

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-05T14:00:09', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd17391a9-77d6-424a-a4fa-fc0498d79c0d'	System	05 Dec 2020 20:00:16
User entered 'No (N)'	System	05 Dec 2020 20:00:16

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-05T14:00:11', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'd17391a9-77d6-424a-a4fa-fc0498d79c0d' User entered '05 Dec 2020 14:00:11'	System	05 Dec 2020 20:00:16
	System	05 Dec 2020 20:00:16

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-12T06:04:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '21e89809-7ea1-446f-831d-0fb6267fd199'	System	12 Dec 2020 12:04:14
User entered 'No (N)'	System	12 Dec 2020 12:04:14

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-12T06:04:09', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '21e89809-7ea1-446f-831d-0fb6267fd199'	System	12 Dec 2020 12:04:14
User entered 'No (N)'	System	12 Dec 2020 12:04:14

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-12T06:04:12', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '21e89809-7ea1-446f-831d-0fb6267fd199' User entered '12 Dec 2020 06:04:12'	System	12 Dec 2020 12:04:14
	System	12 Dec 2020 12:04:14

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-19T07:38:10', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '028ccddf-6d13-4170-a1c7-df6dbbe17c08' User entered 'No (N)'	System	19 Dec 2020 13:38:18
	System	19 Dec 2020 13:38:18

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-19T07:38:13', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '028ccddf-6d13-4170-a1c7-df6dbbe17c08'	System	19 Dec 2020 13:38:18
User entered 'No (N)'	System	19 Dec 2020 13:38:18

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-19T07:38:15', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '028ccddf-6d13-4170-a1c7-df6dbbe17c08' User entered '19 Dec 2020 07:38:15'	System	19 Dec 2020 13:38:18
	System	19 Dec 2020 13:38:18

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-26T07:40:28', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '52617a3d-c56b-4682-86d5-8b374c641025' User entered 'No (N)'	System	26 Dec 2020 13:40:37
	System	26 Dec 2020 13:40:37

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-26T07:40:30', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '52617a3d-c56b-4682-86d5-8b374c641025'	System	26 Dec 2020 13:40:37
User entered 'No (N)'	System	26 Dec 2020 13:40:37

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2020-12-26T07:40:32', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '52617a3d-c56b-4682-86d5-8b374c641025' User entered '26 Dec 2020 07:40:32'	System	26 Dec 2020 13:40:37
	System	26 Dec 2020 13:40:37

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-02T10:36:42', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ccb37bb7-c934-4ec2-987b-a0a42f856af8' User entered 'No (N)'	System	02 Jan 2021 16:36:52
	System	02 Jan 2021 16:36:52

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-02T10:36:45', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ccb37bb7-c934-4ec2-987b-a0a42f856af8' User entered 'No (N)'	System	02 Jan 2021 16:36:52

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-02T10:36:49', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'ccb37bb7-c934-4ec2-987b-a0a42f856af8' User entered '02 Jan 2021 10:36:49'	System	02 Jan 2021 16:36:52
	System	02 Jan 2021 16:36:52

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-11T11:05:53', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9109ec2b-8e2e-40fb-8a88-49529d71f545' User entered 'No (N)'	System	11 Jan 2021 17:06:12
	System	11 Jan 2021 17:06:12

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-11T11:06:03', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9109ec2b-8e2e-40fb-8a88-49529d71f545'	System	11 Jan 2021 17:06:12
User entered 'No (N)'	System	11 Jan 2021 17:06:12

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-11T11:06:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9109ec2b-8e2e-40fb-8a88-49529d71f545' User entered '11 Jan 2021 11:06:07'	System	11 Jan 2021 17:06:12
	System	11 Jan 2021 17:06:12

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-16T21:24:11', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9d72fa92-aa5f-4bba-ab31-0c3caf7dd603' User entered 'No (N)'	System	17 Jan 2021 03:24:20
	System	17 Jan 2021 03:24:20

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-16T21:24:12', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9d72fa92-aa5f-4bba-ab31-0c3caf7dd603'	System	17 Jan 2021 03:24:20
User entered 'No (N)'	System	17 Jan 2021 03:24:20

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-16T21:24:15', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '9d72fa92-aa5f-4bba-ab31-0c3caf7dd603'	System	17 Jan 2021 03:24:20
User entered '16 Jan 2021 21:24:15'	System	17 Jan 2021 03:24:20

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-23T05:50:06', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '259c6c91-1767-4851-b6ae-7e46f44def50'	System	23 Jan 2021 11:50:28
User entered 'No (N)'	System	23 Jan 2021 11:50:28

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-23T05:50:19', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '259c6c91-1767-4851-b6ae-7e46f44def50'	System	23 Jan 2021 11:50:28
User entered 'No (N)'	System	23 Jan 2021 11:50:28

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-23T05:50:24', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '259c6c91-1767-4851-b6ae-7e46f44def50' User entered '23 Jan 2021 05:50:24'	System	23 Jan 2021 11:50:28
	System	23 Jan 2021 11:50:28

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-30T05:40:59', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c658a641-fa68-4710-8a73-6848927e8dc8' User entered 'No (N)'	System	30 Jan 2021 11:41:10
	System	30 Jan 2021 11:41:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-30T05:41:04', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c658a641-fa68-4710-8a73-6848927e8dc8' User entered 'No (N)'	System	30 Jan 2021 11:41:10
	System	30 Jan 2021 11:41:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-01-30T05:41:06', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c658a641-fa68-4710-8a73-6848927e8dc8' User entered '30 Jan 2021 05:41:06'	System	30 Jan 2021 11:41:10
	System	30 Jan 2021 11:41:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-09T08:05:02', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '27e27d9c-e362-49e6-a004-e4e57c489e63' User entered 'No (N)'	System	09 Feb 2021 14:05:12
	System	09 Feb 2021 14:05:12

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-09T08:05:04', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '27e27d9c-e362-49e6-a004-e4e57c489e63' User entered 'No (N)'	System	09 Feb 2021 14:05:12

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-09T08:05:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '27e27d9c-e362-49e6-a004-e4e57c489e63' User entered '09 Feb 2021 08:05:07'	System	09 Feb 2021 14:05:12
	System	09 Feb 2021 14:05:12

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-13T11:47:24', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3ebee081-97b2-4766-8f99-21918becbe9d' User entered 'No (N)'	System	13 Feb 2021 17:47:36
	System	13 Feb 2021 17:47:36

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-13T11:47:28', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3ebee081-97b2-4766-8f99-21918becbe9d' User entered 'No (N)'	System	13 Feb 2021 17:47:36

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-13T11:47:31', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3ebee081-97b2-4766-8f99-21918becbe9d' User entered '13 Feb 2021 11:47:31'	System	13 Feb 2021 17:47:36
	System	13 Feb 2021 17:47:36

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-20T13:00:03', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2dc229bd-5ab2-4249-8858-ec30f5e856f3'	System	20 Feb 2021 19:00:10
User entered 'No (N)'	System	20 Feb 2021 19:00:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-20T13:00:05', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2dc229bd-5ab2-4249-8858-ec30f5e856f3' User entered 'No (N)'	System	20 Feb 2021 19:00:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-20T13:00:07', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2dc229bd-5ab2-4249-8858-ec30f5e856f3' User entered '20 Feb 2021 13:00:07'	System	20 Feb 2021 19:00:10
	System	20 Feb 2021 19:00:10

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-27T07:33:32-06:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '699a142c-1733-454f-9a28-f8c869aa81fb' User entered 'No (N)'	System	27 Feb 2021 13:33:42

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-27T07:33:35-06:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '699a142c-1733-454f-9a28-f8c869aa81fb' User entered 'No (N)'	System	27 Feb 2021 13:33:42

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-27T07:33:38-06:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '699a142c-1733-454f-9a28-f8c869aa81fb' User entered '27 Feb 2021 13:33:38'	System	27 Feb 2021 13:33:42
	System	27 Feb 2021 13:33:42

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-06T15:27:36-06:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'df21b6f3-a800-4376-907f-3d4954a3176a'	System	06 Mar 2021 21:27:44
User entered 'No (N)'	System	06 Mar 2021 21:27:44

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-06T15:27:38-06:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'df21b6f3-a800-4376-907f-3d4954a3176a'	System	06 Mar 2021 21:27:44
User entered 'No (N)'	System	06 Mar 2021 21:27:44

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-06T15:27:41-06:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'df21b6f3-a800-4376-907f-3d4954a3176a'	System	06 Mar 2021 21:27:44
User entered '06 Mar 2021 15:27:41'	System	06 Mar 2021 21:27:44

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-16T06:18:28-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3d8fd3fe-12fc-4673-b145-e77d04b7c268'	System	16 Mar 2021 11:18:36
User entered 'No (N)'	System	16 Mar 2021 11:18:36

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-16T06:18:31-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3d8fd3fe-12fc-4673-b145-e77d04b7c268'	System	16 Mar 2021 11:18:36
User entered 'No (N)'	System	16 Mar 2021 11:18:36

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-16T06:18:34-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '3d8fd3fe-12fc-4673-b145-e77d04b7c268'	System	16 Mar 2021 11:18:36
User entered '16 Mar 2021 06:18:34'	System	16 Mar 2021 11:18:36

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-20T07:18:00-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e973e342-1532-40b0-91f3-9d1912e09d1b'	System	20 Mar 2021 12:18:15
User entered 'No (N)'	System	20 Mar 2021 12:18:15

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-20T07:18:01-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e973e342-1532-40b0-91f3-9d1912e09d1b'	System	20 Mar 2021 12:18:15
User entered 'No (N)'	System	20 Mar 2021 12:18:15

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-20T07:18:09-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'e973e342-1532-40b0-91f3-9d1912e09d1b'	System	20 Mar 2021 12:18:15
User entered '20 Mar 2021 07:18:09'	System	20 Mar 2021 12:18:15

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-27T06:51:54-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4f9f0172-7b5c-4ed9-b277-49dfd4e6dc82'	System	27 Mar 2021 11:52:02
User entered 'No (N)'	System	27 Mar 2021 11:52:02

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-27T06:51:56-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4f9f0172-7b5c-4ed9-b277-49dfd4e6dc82'	System	27 Mar 2021 11:52:02
User entered 'No (N)'	System	27 Mar 2021 11:52:02

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-03-27T06:51:58-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '4f9f0172-7b5c-4ed9-b277-49dfd4e6dc82'	System	27 Mar 2021 11:52:02
User entered '27 Mar 2021 06:51:58'	System	27 Mar 2021 11:52:02

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-04T18:23:16-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6837c937-0532-430b-8f9a-1f5582a446e3' User entered 'No (N)'	System	04 Apr 2021 23:23:23
	System	04 Apr 2021 23:23:23

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-04T18:23:18-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6837c937-0532-430b-8f9a-1f5582a446e3' User entered 'No (N)'	System	04 Apr 2021 23:23:23
	System	04 Apr 2021 23:23:23

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-04T18:23:21-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '6837c937-0532-430b-8f9a-1f5582a446e3'	System	04 Apr 2021 23:23:23
User entered '04 Apr 2021 18:23:21'	System	04 Apr 2021 23:23:23

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-10T07:35:31-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2d328081-2f83-472a-8b6a-c4eec2e4f4af' User entered 'No (N)'	System	10 Apr 2021 12:35:38

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-10T07:35:33-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2d328081-2f83-472a-8b6a-c4eec2e4f4af' User entered 'No (N)'	System	10 Apr 2021 12:35:38

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-10T07:35:36-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '2d328081-2f83-472a-8b6a-c4eec2e4f4af' User entered '10 Apr 2021 07:35:36'	System	10 Apr 2021 12:35:38
	System	10 Apr 2021 12:35:38

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-17T20:59:28-04:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '10963cc5-fe8b-4def-a70f-4e3397ba0454'	System	18 Apr 2021 00:59:40
User entered 'No (N)'	System	18 Apr 2021 00:59:40

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-17T20:59:29-04:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '10963cc5-fe8b-4def-a70f-4e3397ba0454'	System	18 Apr 2021 00:59:40
User entered 'No (N)'	System	18 Apr 2021 00:59:40

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-17T20:59:32-04:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '10963cc5-fe8b-4def-a70f-4e3397ba0454'	System	18 Apr 2021 00:59:40
User entered '17 Apr 2021 20:59:32'	System	18 Apr 2021 00:59:40

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-24T08:55:36-04:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '370a36b4-6785-4ef2-b18a-2aa92ce23fae' User entered 'No (N)'	System	24 Apr 2021 12:55:43

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-24T08:55:37-04:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '370a36b4-6785-4ef2-b18a-2aa92ce23fae' User entered 'No (N)'	System	24 Apr 2021 12:55:43

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-04-24T08:55:40-04:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '370a36b4-6785-4ef2-b18a-2aa92ce23fae' User entered '24 Apr 2021 08:55:40'	System	24 Apr 2021 12:55:43
	System	24 Apr 2021 12:55:43

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-05-01T20:10:31-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c50aff92-f12f-4c1d-aa28-23b367878983'	System	02 May 2021 01:14:19
User entered 'Yes (Y)'	System	02 May 2021 01:14:19

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

Have you been exposed to someone with 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-05-01T20:10:38-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c50aff92-f12f-4c1d-aa28-23b367878983'	System	02 May 2021 01:14:19
User entered 'No (N)'	System	02 May 2021 01:14:19

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-05-01T20:10:43-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c50aff92-f12f-4c1d-aa28-23b367878983'	System	02 May 2021 01:14:19
User entered 'No (N)'	System	02 May 2021 01:14:19

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-05-01T20:10:52-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c50aff92-f12f-4c1d-aa28-23b367878983'	System	02 May 2021 01:14:19
User entered 'Yes (Y)'	System	02 May 2021 01:14:19

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Please 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 (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-05-01T20:11:09-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c50aff92-f12f-4c1d-aa28-23b367878983'	System	02 May 2021 01:14:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 May 2021 01:14:19

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-05-01T20:11:14-05:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: 'c50aff92-f12f-4c1d-aa28-23b367878983'	System	02 May 2021 01:14:19
User entered '01 May 2021 20:11:14'	System	02 May 2021 01:14:19

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 06:56:26

US3292173

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:27:36

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 06:56:26
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 06:56:26

US3292173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:27:36

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 22:52:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-27T07:33:53-06:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '599e3deb-ccb5-4cde-9183-cb72b710d2ef' User entered 'No (N)'	System	01 Mar 2021 22:02:10
	System	01 Mar 2021 22:02:10

US3292173

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:27:36

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:52:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (818EC357-3325-40C8-92E6-3ECF2882D5E0)', Time: '2021-02-27T07:33:57-06:00', User OID: 'PatientReportedOutcome (US3292173)', ODM File OID: '599e3deb-ccb5-4cde-9183-cb72b710d2ef' User entered '27 Feb 2021 13:33:57'	System	01 Mar 2021 22:02:10
	System	01 Mar 2021 22:02:10

US3292173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	13 Nov 2020 17:30:08

US3292173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4), (b) (6)	04 Dec 2020 16:18:41
Query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered with 'date is correct as is' (Site from System).	Kevin Martinez (b) (4)	13 Nov 2020 22:27:32
User opened query 'Safety Call Day 85 'Date of Contact or Contact Attempt' is less than 53 days or greater than 59 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	13 Nov 2020 17:30:08
User entered '11 Nov 2020'	Gerardo Pena (b) (4)	13 Nov 2020 17:30:08

US3292173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	13 Nov 2020 17:30:08

US3292173

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	13 Nov 2020 17:30:08

US3292173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	13 Nov 2020 17:30:52

US3292173

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 01:09:58
User entered 'l'	System	13 Nov 2020 17:30:52

US3292173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 16:04:18

US3292173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '11 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	15 Dec 2020 16:04:18

US3292173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 16:04:18

US3292173

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	15 Dec 2020 16:04:18

US3292173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Dec 2020 16:05:59

US3292173

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User entered 'l'	System	15 Dec 2020 16:05:59

US3292173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 15:40:04

US3292173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '11 Jan 2021'	(b) (4), (b) (6)	13 Jan 2021 15:40:04

US3292173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	13 Jan 2021 15:40:04

US3292173

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	13 Jan 2021 15:40:04

US3292173

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	13 Jan 2021 15:40:09

US3292173

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User entered 'l'	System	13 Jan 2021 15:40:09

US3292173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 19:16:21

US3292173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	10 Feb 2021 19:16:21

US3292173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	10 Feb 2021 19:16:21

US3292173

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	10 Feb 2021 19:16:21

US3292173

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	10 Feb 2021 19:16:26

US3292173

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 03:58:06
User entered 'l'	System	10 Feb 2021 19:16:26

US3292173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:18

US3292173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered '12 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:18

US3292173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[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 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:18

US3292173

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User entered 'VISIT4'	System	15 Mar 2021 18:40:18

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User entered empty.	System	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User entered empty.	System	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User entered empty.	System	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User entered empty.	System	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User entered empty.	System	31 Mar 2021 19:37:53

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58

US3292173

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58

US3292173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:23

US3292173

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered empty.	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:23

US3292173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:35

US3292173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered '12 Mar 2021'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:35

US3292173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered '08:36'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:35

US3292173

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User entered '12 Mar 2021 08:36'	System	15 Mar 2021 18:40:35

US3292173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:11:37
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	15 Mar 2021 18:40:38

US3292173

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:58:58
User entered 'I'	System	15 Mar 2021 18:40:38

US3292173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:37:33

US3292173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '8 Apr 2021'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:37:33

US3292173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:37:33

US3292173

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:37:33

US3292173

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	13 Apr 2021 16:37:42

US3292173

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	13 Apr 2021 16:37:42

US3292173

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

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:34:41

US3292173

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

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:34:41

US3292173

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

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[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 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Feb 2021 17:34:41

US3292173

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

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'UNBLND_DECIDE'	System	09 Feb 2021 17:34:41

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:35:08

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 04:57:29

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
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	09 Feb 2021 17:36:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Feb 2021 17:36:07
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Feb 2021 17:35:08
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:35:08

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:36:48
Data hard locked.	(b) (4)	
	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User closed query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		26 Apr 2021 14:59:47
Query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	23 Apr 2021 06:54:50
Signature has been broken.	(b) (4)	
	Dawn Killian (b) (4)	23 Apr 2021 06:54:44
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Dawn Killian (b) (4)	23 Apr 2021 06:54:44
User opened query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 04:50:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty. WR# 5295537	(b) (4)	
Amendment Manager inserted this DataPoint.	System	10 Mar 2021 16:55:28
	System	06 Mar 2021 04:57:29

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:35:08

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	09 Feb 2021 17:35:08

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Placebo (Placebo)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 17:35:08

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Placebo (Placebo)'	(b) (4), (b) (6)	09 Feb 2021 17:35:08

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:35:08

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'I'	System	09 Feb 2021 17:35:08

US3292173

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

Form: Unblinding

Generated On: 09 Jun 2021 16:27:36

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'I'	System	09 Feb 2021 17:36:07
User entered empty.	System	09 Feb 2021 17:35:08

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered empty.	System	09 Feb 2021 17:37:12
DataPoint set to visible.	System	09 Feb 2021 17:36:07

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered empty.	System	09 Feb 2021 17:37:12
DataPoint set to visible.	System	09 Feb 2021 17:36:07

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User accepted default value 'Pre-Dose (PREDOSE)'		09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '08:25'	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered '9 Feb 2021 08:25'	System	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '36.1' C	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '73'	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'bpm'	System	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '12'	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'breaths/min'	System	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '118'	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mmHg'	System	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '78'	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mmHg'	System	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered missing code ND - Not Done.	(b) (4), (b) (6)	09 Feb 2021 17:37:12

US3292173

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:27:36

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered empty.	System	09 Feb 2021 17:37:12
DataPoint set to visible.	System	09 Feb 2021 17:36:07

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User accepted default value 'Post-Dose (POSTDOSE)'		09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '10:40'	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered '9 Feb 2021 10:40'	System	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '36.1' C	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '62'	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'bpm'	System	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '16'	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'breaths/min'	System	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '122'	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mmHg'	System	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '83'	(b) (4), (b) (6)	09 Feb 2021 17:38:29

US3292173

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mmHg'	System	09 Feb 2021 17:38:29

US3292173

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:38:37

US3292173

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:38:37

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:38:52

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:38:52

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

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 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 17:38:52

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mRNA-1273'	System	09 Feb 2021 17:38:52
DataPoint set to visible.	System	09 Feb 2021 17:36:07

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:38:52

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '10:09'	(b) (4), (b) (6)	09 Feb 2021 17:38:52

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered '9 Feb 2021 10:09'	System	09 Feb 2021 17:38:52

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
Signature has been broken.	(b) (4), (b) (6)	09 Mar 2021 17:04:50
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Mar 2021 17:04:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	09 Feb 2021 17:38:52

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'ONCE'	System	09 Feb 2021 17:38:52

US3292173

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

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 17:38:52

US3292173

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:39:15

US3292173

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:39:15

US3292173

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '08:36'	(b) (4), (b) (6)	09 Feb 2021 17:39:15

US3292173

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered '9 Feb 2021 08:36'	System	09 Feb 2021 17:39:15

US3292173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:39:29

US3292173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 17:39:29

US3292173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '09:30'	(b) (4), (b) (6)	09 Feb 2021 17:39:29

US3292173

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:27:36

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered '9 Feb 2021 09:30'	System	09 Feb 2021 17:39:29

US3292173

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

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 17:39:33

US3292173

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

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'I'	System	09 Feb 2021 17:39:33

US3292173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 16:16:27

US3292173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '16 Feb 2021'	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 16:16:27

US3292173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 16:16:27

US3292173

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 16:16:27

US3292173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	17 Feb 2021 16:19:06

US3292173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'l'	System	17 Feb 2021 16:19:06

US3292173

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'I'	System	17 Feb 2021 16:19:06
DataPoint set to visible.	System	17 Feb 2021 16:19:06

US3292173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 17:02:54

US3292173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 17:02:54

US3292173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[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 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	09 Mar 2021 17:02:54

US3292173

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'OLD29'	System	09 Mar 2021 17:02:54

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User accepted default value 'Pre-Dose (PREDOSE)'		09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '08:13'	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered '9 Mar 2021 08:13'	System	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '36.5' C	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '73'	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'bpm'	System	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '14'	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'breaths/min'	System	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '136'	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mmHg'	System	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '85'	(b) (4), (b) (6)	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:27:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mmHg'	System	09 Mar 2021 17:03:32

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User accepted default value 'Post-Dose (POSTDOSE)'		09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '09:59'	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered '9 Mar 2021 09:59'	System	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '36.3' C	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Oral (Oral)'	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '63'	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'bpm'	System	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '16'	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'breaths/min'	System	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '121'	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mmHg'	System	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '86'	(b) (4), (b) (6)	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mmHg'	System	09 Mar 2021 17:04:05

US3292173

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 17:04:12

US3292173

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 17:04:12

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

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 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4), (b) (6)	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'mRNA-1273'	System	09 Mar 2021 17:04:32
DataPoint set to visible.	System	17 Feb 2021 16:19:06

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '9 Mar 2021'	(b) (4), (b) (6)	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '09:29'	(b) (4), (b) (6)	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered '9 Mar 2021 09:29'	System	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	(b) (4) System	09 Mar 2021 17:04:50
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	09 Mar 2021 17:04:50
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	09 Mar 2021 17:04:32
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'ONCE'	System	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:27:36

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'INTRAMUSCULAR'	System	09 Mar 2021 17:04:32

US3292173

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Mar 2021 17:05:00

US3292173

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'l'	System	09 Mar 2021 17:05:00

US3292173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 16:06:07

US3292173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '16 Mar 2021'	(b) (4), (b) (6)	17 Mar 2021 16:06:07

US3292173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Mar 2021 16:06:07

US3292173

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:27:36

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4), (b) (6)	17 Mar 2021 16:06:07

US3292173

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Mar 2021 16:09:09

US3292173

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:27:36

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 09:15:50
User entered 'l'	System	17 Mar 2021 16:09:09

US3292173

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:23

US3292173

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:23

US3292173

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[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 14:06:04
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:23

US3292173

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:27:36

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'OLD57'	System	06 Apr 2021 21:13:23

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:27:36

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	06 Apr 2021 21:13:33

US3292173

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:37

US3292173

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:27:36

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered empty.	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:37

US3292173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:53

US3292173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '5 Apr 2021'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:53

US3292173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:06:04
User entered '08:50'	(b) (4) (b) (4), (b) (6)	06 Apr 2021 21:13:53

US3292173

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:27:36

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered '5 Apr 2021 08:50'	System	06 Apr 2021 21:13:53

US3292173

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:27:36

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 May 2021 03:59:59
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:42
Signature has been broken.	(b) (4)	
	Nathan Cortez (b) (4)	02 May 2021 23:07:45
User entered 'Yes (Y)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	02 May 2021 23:07:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4)	
	Dawn Killian (b) (4)	03 Feb 2021 22:14:29
	(b) (4)	

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Disturbances in consciousness NEC, PT: Syncope, LLT: Syncope vasovagal - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	02 May 2021 23:10:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 May 2021 23:10:02
Data point term sent to Coder	System	02 May 2021 23:09:10
User entered 'Vasovagal Syncope'	Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '09 Feb 2021'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	03 May 2021 06:31:42
Query 'Data is required. Please provide.' answered with 'Not within 24 hours of dose' (Site from System).	Nathan Cortez (b) (4)	02 May 2021 23:09:28
User opened query 'Data is required. Please provide.' (Site from System).	System	02 May 2021 23:09:09
User entered empty.	Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '09 Feb 2021'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4), (b) (6)	03 May 2021 06:31:49
Query 'Data is required. Please provide.' answered with 'Not within 24 hours of dose' (Site from System).	Nathan Cortez (b) (4)	02 May 2021 23:09:32
User opened query 'Data is required. Please provide.' (Site from System).	System	02 May 2021 23:09:09
User entered empty.	Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'No (N)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '0'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '0'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '0'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered empty.	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered empty.	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered empty.	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered empty.	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '0'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '0'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '0'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'Related (RELATED)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'None (NONE)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'I'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '0'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered '0'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

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 20:04:29
User entered empty.	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
User entered empty.	(b) (4) Nathan Cortez (b) (4)	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:27:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 May 2021 23:09:09

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:18
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:14
User entered	(b) (4), (b) (6)	03 May 2021 18:58:06
'USA-US072-2021-mRNA-1273-P301000022'	System	03 May 2021 18:58:06
Un-reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:06
User entered 'New' reason for change: Data Entry Error	(b) (4), (b) (6)	03 May 2021 18:58:06
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:56:56
User entered empty.	(b) (4), (b) (6)	03 May 2021 18:56:51

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 19:37:18
User coded data point as SOC: Hepatobiliary disorders, HLGT: Gallbladder disorders, HLT: Cholecystitis and cholelithiasis, PT: Cholecystitis, LLT: Cholecystitis - version MedDRA\\23.0.	Coder Import (b) (4)	02 May 2021 23:13:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	02 May 2021 23:13:03
Data point term sent to Coder	System	02 May 2021 23:12:11
User entered 'Cholecystitis'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'No (N)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'No (N)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '28 Apr 2021'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered empty.	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'No (N)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '28 Apr 2021'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered empty.	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'Grade 3/Severe (Grade 3/Severe)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 May 2021 23:11:42
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	02 May 2021 23:11:18
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '0'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '0'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

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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 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	02 May 2021 23:11:42
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	02 May 2021 23:11:42
User entered '1' reason for change: Data Entry Error	Nathan Cortez (b) (4)	02 May 2021 23:11:42
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	02 May 2021 23:11:18
User entered '0'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '28 Apr 2021'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '30 Apr 2021'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'No (N)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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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 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered empty.	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '0'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '0'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '0'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 19:37:18
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		03 May 2021 18:56:39
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated' (Site from Safety).		03 May 2021 18:49:20
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 18:49:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 18:49:08
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 May 2021 18:49:08
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		03 May 2021 00:46:21
User opened query 'Data is required. Please complete.' (Site from System).	System	02 May 2021 23:11:18
User entered empty.	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 19:37:18
User closed query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		03 May 2021 18:56:42
Query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' answered with 'Updated' (Site from Safety).		03 May 2021 18:49:26
User closed query 'Data is required. Please complete.' (Site from System).	System	03 May 2021 18:49:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 May 2021 18:49:08
User entered 'Not Related (NOT RELATED)' reason for change: Per Query Resolution	(b) (4), (b) (6)	03 May 2021 18:49:08
User opened query 'PV Query Urgent: Please provide missing causality assessment for the event as soon as possible.' (Site from Safety).		03 May 2021 00:46:35
User opened query 'Data is required. Please complete.' (Site from System).	System	02 May 2021 23:11:18
User entered empty.	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'None (NONE)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '0'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered '0'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'I'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

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 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered empty.	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:18
User entered 'Subject stated he had an emergency cholecystectomy for cholecystitis on 28 Apr 2021 and was admitted for 2 nghts @ North Central Baptist. Tramadol 50mg po prn. was prescribed at discharge for pain.'	Nathan Cortez (b) (4)	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 May 2021 23:11:18

US3292173

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	02 May 2021 23:11:18

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:27:36

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	02 May 2021 23:11:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:27:36

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 10:14:19
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4), (b) (6)	15 Aug 2020 01:47:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Sep 2020 10:13:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 10:13:46
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4)	21 Sep 2020 18:13:54 21 Sep 2020 18:12:58
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: LORATADINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 07:00:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 07:00:12
Data point term sent to Coder User entered 'Loratadine'	System (b) (4), (b) (6)	15 Aug 2020 01:49:55 15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Per DM CLR: Please update the indication to reflect the type of RHINITIS (Allergic or Infective). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	06 Oct 2020 11:52:51
Query 'Per DM CLR: Please update the indication to reflect the type of RHINITIS (Allergic or Infective). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	21 Sep 2020 18:13:10
User entered 'RHINITIS (Allergic)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	21 Sep 2020 18:12:58
User opened query 'Per DM CLR: Please update the indication to reflect the type of RHINITIS (Allergic or Infective). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:46:14
User entered 'Rhinitis'		15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '10'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'UN UNK 2004' reason for change: Data Entry Error	(b) (4) Dawn Killian (b) (4)	21 Sep 2020 18:15:25
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 13:07:03
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 01:59:12
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 01:49:30
User entered 'Un UNK 1986'	(b) (4), (b) (6)	15 Aug 2020 01:49:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:49:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Aug 2020 01:49:30

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

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[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 01:49:30

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 06:41:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 06:41:16
Data point term sent to Coder	System	15 Aug 2020 01:50:56
User entered 'Omeprazole'	(b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	06 Oct 2020 11:53:17
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	21 Sep 2020 18:14:34
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:56:36
User entered 'Acid Reflux'	(b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

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[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '20'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 18:54:23
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	26 Oct 2020 19:27:06
User entered 'UN UNK 2004' reason for change: Data Entry Error	Dawn Killian (b) (4)	26 Oct 2020 19:27:01
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:28:06
User entered 'UN UNK 1986' reason for change: Data Entry Error	Dawn Killian (b) (4)	21 Sep 2020 18:14:28
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4), (b) (6)	16 Aug 2020 13:07:07
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered' (Site from System).		15 Aug 2020 01:59:07
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 01:50:41
User entered 'Un UNK 2004'	(b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 01:50:41

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, ATC: OTHER PLAIN VITAMIN PREPARATIONS, PRODUCT: NICOTINIC ACID, PRODUCTSYNONYM: NIACIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 01:52:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 01:52:08
Data point term sent to Coder	System	15 Aug 2020 01:51:56
User entered 'Niacin'	(b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:38
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 10:15:40
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:01:50
Signature has been broken.	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:01:44
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:01:44
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:53:21
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'General Health'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '250'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 13:07:10
answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 01:59:02
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 01:51:34
User entered 'Un Apr 2020'	(b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 01:51:34

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 01:54:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 01:54:08
Data point term sent to Coder	System	15 Aug 2020 01:52:57
User entered 'Multi vitamin'	(b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:38
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 10:15:50
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:01:59
Signature has been broken.	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:01:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:01:55
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:53:31
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'General health'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '2'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 13:07:13
answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 01:58:56
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 01:52:38
User entered 'Un UNK 1980'	(b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 01:52:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 01:54:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 01:54:08
Data point term sent to Coder	System	15 Aug 2020 01:53:58
User entered 'Aspirin'	(b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	29 Apr 2021 17:56:38
User closed query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4) (b) (4), (b) (6)	29 Apr 2021 10:15:55
Query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:02:09
Signature has been broken.	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:02:05
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 11:02:05
User opened query 'Per CDM: Please review the response as this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 07:53:41
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'General Health'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '81'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 13:07:17
answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 01:58:52
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 01:53:24
User entered 'Un Apr 2020'	(b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 01:53:24

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: PLANTAGO OVATA, PRODUCTSYNONYM: METAMUCIL [PLANTAGO OVATA] - version WHODrug-Global-B3\202003.	(b) (4) Coder Import (b) (4)	29 Sep 2020 09:39:00
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 Sep 2020 09:39:00
Data point term sent to Coder	System	21 Sep 2020 18:17:04
User entered 'METAMUCIL (psyllium husk powder)' reason for change: New Information	Dawn Killian (b) (4) (b) (4)	21 Sep 2020 18:17:00
Data point term sent to Coder	System	18 Sep 2020 17:50:40
User closed query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	System	18 Sep 2020 17:49:56
Query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' answered with 'updated' (Site from System).	Victoria Hernandez (b) (4) (b) (4)	18 Sep 2020 17:49:56
Data point term sent to Coder	System	18 Sep 2020 17:49:34
User entered 'METAMUCIL psyllium husk (Plantago ovata) 0.6 g. Nonmedicinal ingredients: acesulfame potassium, aspartame, citric acid, FD&C Red No. 40, maltodextrin, and natural lemon flavour. Each capsule contains psyllium husk (Plantago ovata) 525 mg' (non-conformant).	Victoria Hernandez (b) (4) (b) (4)	18 Sep 2020 17:49:02
User opened query 'CDM Coding: This medication can be referred as multiple ingredients in the standard coding dictionary. Please enter all the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.' (Site from System).	Coder Import (b) (4) (b) (4)	17 Aug 2020 11:36:03
Data point term sent to Coder	System	15 Aug 2020 01:54:58
PRODUCTION RELEASE (v12.003 EAB) (1725)		2025 of 2130

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Metamucil'	(b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Per DM CLR: Prophylaxis = No. Please review if this indication should be changed to Yes as this medication was used for 'DIGESTIVE HEALTH'. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	25 Nov 2020 18:39:16
Query 'Per DM CLR: Prophylaxis = No. Please review if this indication should be changed to Yes as this medication was used for 'DIGESTIVE HEALTH'. If yes, please update 'Prophylaxis' as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	26 Oct 2020 19:27:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	26 Oct 2020 19:27:26
User opened query 'Per DM CLR: Prophylaxis = No. Please review if this indication should be changed to Yes as this medication was used for 'DIGESTIVE HEALTH'. If yes, please update 'Prophylaxis' as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 07:29:00
User entered 'No (N)'		15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Digestive health'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '2'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Scoops'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 13:07:20
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 01:58:46
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 01:54:27
User entered 'Un UNK 2004'	(b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 01:54:27

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Sep 2020 18:18:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Sep 2020 18:18:49
Data point term sent to Coder Coding entries removed.	System Dawn Killian (b) (4) (b) (4)	21 Sep 2020 18:18:05 21 Sep 2020 18:17:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 07:29:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Aug 2020 07:29:08
Data point term sent to Coder User entered 'Ibuprofen'	System (b) (4), (b) (6)	15 Aug 2020 01:55:59 15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
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)	16 Nov 2020 15:15:51
User closed query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE ACHE (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		16 Nov 2020 15:15:49
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).	Dawn Killian (b) (4)	21 Sep 2020 18:17:38
Query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE ACHE (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	21 Sep 2020 18:17:32
User entered 'Generalized MUSCLE ACHEs' reason for change: Data Entry Error	Dawn Killian (b) (4)	21 Sep 2020 18:17:26
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).	(b) (4), (b) (6)	21 Sep 2020 06:39:51
User opened query 'Per DM CLR: Please update the indication to reflect the location of MUSCLE ACHE (e.g. Generalized or Localized- specify part or area). Review and update indication and ensure to update MH/Adverse event eCRF as appropriate. ' (Site from DM).		21 Sep 2020 06:38:38
User entered 'Muscle ache'		15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Nov 2020 17:13:44
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	26 Oct 2020 19:28:52
User entered '400' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	26 Oct 2020 19:28:43
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:11:33
User entered '2'		15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'mg (mg)' reason for change: Data Entry Error	(b) (4) Dawn Killian (b) (4)	26 Oct 2020 19:28:43
User entered 'tablet (TABLET)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	16 Aug 2020 13:07:24
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 01:58:40
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 01:55:25
User entered 'Un UNK 2018'	(b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Aug 2020 01:55:25

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: UROLOGICALS, ATC: DRUGS USED IN ERECTILE DYSFUNCTION, PRODUCT: TADALAFIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Aug 2020 01:59:09
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Aug 2020 01:59:09
Data point term sent to Coder	System	15 Aug 2020 01:58:01
User entered 'Tadalafil'	(b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Erectile dysfunction'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '20'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	(b) (4)	
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.'	(b) (4), (b) (6)	16 Aug 2020 13:07:28
answered with 'Medication is ongoing, correct as entered' (Site from System).	(b) (4), (b) (6)	15 Aug 2020 01:58:33
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	15 Aug 2020 01:57:23
User entered 'Un UNK 2009'	(b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Aug 2020 01:57:23

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 20:08:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	28 Sep 2020 20:08:48
Data point term sent to Coder	System	28 Sep 2020 20:07:51
User entered 'Influenza Vaccine'	Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Yes (Y)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Influenza'	(b) (4) Kristy Trevino (b) (4) (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '.5'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 17:36:41
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	26 Oct 2020 19:30:53
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	26 Oct 2020 19:30:44
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication (consider mL). Please update the unit as appropriate or provide explanation for alternate unit.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 13:58:36
User closed query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 20:08:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	28 Sep 2020 20:08:20
User entered 'mg (mg)' reason for change: Data Entry Error	Kristy Trevino (b) (4)	28 Sep 2020 20:08:20
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Sep 2020 20:07:38
User entered empty.	Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'once (ONCE)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered empty.	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '27 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '0'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered '27 Sep 2020'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) Kristy Trevino (b) (4)	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User entered empty.	System	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User entered empty.	System	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:27:36

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	23 Apr 2021 07:54:14
User entered empty.	System	28 Sep 2020 20:07:38

US3292173

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:27:36

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 19:57:53
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	04 Feb 2021 16:32:23

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 19:37:28
Reviewed for Safety.		03 May 2021 18:58:45
User entered 'USA-US072-2021-MRNA-1273-P301000022'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'Yes (Y)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 19:37:28
Reviewed for Safety.		03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 19:37:28
Reviewed for Safety.		03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'Yes (Y)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 19:37:28
Reviewed for Safety.		03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 May 2021 19:37:28
Reviewed for Safety.		03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'No (N)'		03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'Douglas'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'Denham'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered '7940 Floyd Curl Drive'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'San Antonio'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered '78229'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:28
User entered 'US'	System	03 May 2021 18:59:27

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:59:27

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'USA-US072-2021-MRNA-1273-P301000022'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'Yes (Y)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'Yes (Y)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'No (N)'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'Douglas'		03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered 'Denham'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered '7940 Floyd Curl Drive'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 19:37:28
Reviewed for Safety.		03 May 2021 18:58:45
User entered 'San Antonio'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:58:45
User entered '78229'	System	03 May 2021 18:58:06

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:28
User entered 'US'	System	03 May 2021 18:59:27

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form

Generated On: 09 Jun 2021 16:27:36

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 May 2021 18:59:27

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:27:36

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 20:04:29
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 May 2021 19:37:28
User entered '03/May/2021 14:59'	System	03 May 2021 18:59:27

US3292173

Folder: SAE USA-US072-2021-MRNA-1273-P301000022

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:27:36

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 20:04:29
DataPoint Verified.	(b) (4)	03 May 2021 19:37:28
Un-reviewed for Safety.	(b) (4), (b) (6)	03 May 2021 18:59:27
User entered '1' reason for change: Data Entry Error		03 May 2021 18:59:27
Reviewed for Safety.		03 May 2021 18:59:10
User entered '0'		03 May 2021 18:58:56