

US3292236 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:28:29

All time stamps listed in this document are displayed in GMT

US3292236

Form: Participant Creation

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

[Participant ID](#)

US3292236

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

US3292236

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: Screening

Form: Demographics

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Date of Birth (MMM yyyy)	(b) (6) 1940
Age	80
Age Units	YEARS
Age (Derived)	80
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

US3292236

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3292236

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Were any significant conditions reported?

Yes ☒

No ☐

US3292236

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1972
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 1972
Start Year (derived)	1972
Stop Month and Year (derived)	
Stop Year (derived)	

US3292236

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	ALLERGIES TO SOY
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

US3292236

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	HYSTERECTOMY
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

US3292236

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	HOSPITALIZATION - PNEUMONIA
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1990
Start Year (derived)	1990
Stop Month and Year (derived)	JAN 1990
Stop Year (derived)	1990

US3292236

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	HOSPITALIZATION - PNEUMONIA
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

US3292236

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	CATARACT REMOVAL OU - BILATERAL
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

US3292236

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	UPPER GI BLEED
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

US3292236

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	BILATERAL HEARING LOSS
Start date (dd MMM yyyy)	UN UNK 1990
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 1990
Start Year (derived)	1990
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292236

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	CATARACTS OU
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

US3292236

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	STOMACH ULCER
Start date (dd MMM yyyy)	UN UNK 1986
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 1986
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 1986
Stop Year (derived)	1986

US3292236

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292236

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	SQUAMOUS CELL CANCER - RLE
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

US3292236

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	MIGRAINE HEADACHES
Start date (dd MMM yyyy)	UN UNK 1987
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 1987
Start Year (derived)	1987
Stop Month and Year (derived)	
Stop Year (derived)	

US3292236

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Condition	UTERINE FIBROIDS
Start date (dd MMM yyyy)	UN UNK 1979
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 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

US3292236

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	08:36 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 08:36
Height (xxx.x)	171.0 cm
Weight (xxx.x)	59.7 kg
BMI (xxx.x)	20.41654 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)	

US3292236

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

20 AUG 2020

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

US3292236

Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Date of assessment (dd MMM yyyy) 20 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 1979

Date of surgery unknown False

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

Date of last menstruation unknown False

US3292236

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

US3292236

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

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	

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

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

What was the participant's randomization number? 187235

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 ☒

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Height	ND - Not Done
Weight	ND - Not Done

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Height	ND - Not Done
Weight	ND - Not Done
Timepoint	Pre-Dose <input checked="" type="radio"/> Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Date of assessment (dd MMM yyyy)	20 AUG 2020
Time of assessment (00:00-23:59)	09:14 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 09:14
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

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)	20 AUG 2020
Time of assessment (00:00-23:59)	10:47 (24 HR)
Vital Signs Date and Time (derived)	20 AUG 2020 10:47
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)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3292236

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

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.

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 21:15:39

Generated On: 09 Jun 2021 16:28:29

Was study treatment given? Yes ☒ No ☐

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

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:14 (24 HR)

Treatment Date and Time (derived) 20 AUG 2020 10:14

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

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	20 AUG 2020
Collection time (00:00-23:59)	09:37 (24 HR)
Collection date and time (derived)	20 AUG 2020 09:37

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 21:15:39

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)			20 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:27	20 AUG 2020 09:27
Nasopharyngeal Swab 2	No		

US3292236

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:39

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 AUG 2020 10:59

PC Open Date & Time

20 AUG 2020 10:34

PC Close Date & Time

20 AUG 2020 13:04

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 97.3 °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	20 AUG 2020 18:27
PC Open Date & Time	20 AUG 2020 13:59
PC Close Date & Time	21 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

21 AUG 2020 15:04

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 AUG 2020 18:02

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °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

23 AUG 2020 18:05

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

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

24 AUG 2020 19:29

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 17:26

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

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

97.2 °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

26 AUG 2020 18:19

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 11:00

PC Open Date & Time

20 AUG 2020 10:34

PC Close Date & Time

20 AUG 2020 13:04

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

20 AUG 2020 18:28

PC Open Date & Time

20 AUG 2020 13:59

PC Close Date & Time

21 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 AUG 2020 15:03

PC Open Date & Time

21 AUG 2020 12:00

PC Close Date & Time

22 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 AUG 2020 18:03

PC Open Date & Time

22 AUG 2020 12:00

PC Close Date & Time

23 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

23 AUG 2020 18:06

PC Open Date & Time

23 AUG 2020 12:00

PC Close Date & Time

24 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

24 AUG 2020 19:29

PC Open Date & Time

24 AUG 2020 12:00

PC Close Date & Time

25 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

25 AUG 2020 17:26

PC Open Date & Time

25 AUG 2020 12:00

PC Close Date & Time

26 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 18:20

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 11:01
PC Open Date & Time	20 AUG 2020 10:34
PC Close Date & Time	20 AUG 2020 13:04

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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

No ☒

Yes ☐

PC Time stamp	20 AUG 2020 18:30
PC Open Date & Time	20 AUG 2020 13:59
PC Close Date & Time	21 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 2333

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	21 AUG 2020 15:05
PC Open Date & Time	21 AUG 2020 12:00
PC Close Date & Time	22 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

59 of 2333

EAB) (1725)

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	22 AUG 2020 18:04
PC Open Date & Time	22 AUG 2020 12:00
PC Close Date & Time	23 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

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)

61 of 2333

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	23 AUG 2020 18:06
PC Open Date & Time	23 AUG 2020 12:00
PC Close Date & Time	24 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

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

63 of 2333

EAB) (1725)

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	24 AUG 2020 19:30
PC Open Date & Time	24 AUG 2020 12:00
PC Close Date & Time	25 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

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

65 of 2333

EAB) (1725)

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	25 AUG 2020 17:27
PC Open Date & Time	25 AUG 2020 12:00
PC Close Date & Time	26 AUG 2020 11:59

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

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 ☒

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 18:21
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

03 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted? Yes ☒ No ☐

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

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

Comments PATIENT DID NOT ANSWER CALL.

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	17 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	09:32 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 09:32
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	116 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Timepoint	Pre-Dose <input type="checkbox"/>
	Post-Dose <input checked="" type="checkbox"/>
Were vital signs assessed?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>
Date of assessment (dd MMM yyyy)	17 SEP 2020
Time of assessment (00:00-23:59)	11:21 (24 HR)
Vital Signs Date and Time (derived)	17 SEP 2020 11:21
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	64 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	121 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	65 mmHg
Diastolic Blood Pressure units	MMHG

US3292236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

17 SEP 2020

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

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

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

What was the treatment time? (00:00-23:59) 10:49 (24 HR)

Treatment Date and Time (derived) 17 SEP 2020 10:49

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

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

17 SEP 2020

Collection time (00:00-23:59)

09:42 (24 HR)

Collection date and time (derived)

17 SEP 2020 09:42

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

17 SEP 2020 11:26

PC Open Date & Time

17 SEP 2020 11:09

PC Close Date & Time

17 SEP 2020 13:39

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 94.4 °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	17 SEP 2020 15:44
PC Open Date & Time	17 SEP 2020 14:34
PC Close Date & Time	18 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

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

18 SEP 2020 16:20

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

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

97.8 °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 SEP 2020 21:03

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

20 SEP 2020 18:54

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

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

97.8 °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

21 SEP 2020 17:20

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

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

97.6 °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

22 SEP 2020 17:34

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

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

24 SEP 2020 06:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

17 SEP 2020 11:26

PC Open Date & Time

17 SEP 2020 11:09

PC Close Date & Time

17 SEP 2020 13:39

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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

17 SEP 2020 15:45

PC Open Date & Time

17 SEP 2020 14:34

PC Close Date & Time

18 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 2

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

18 SEP 2020 16:21

PC Open Date & Time

18 SEP 2020 12:00

PC Close Date & Time

19 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

19 SEP 2020 21:03

PC Open Date & Time

19 SEP 2020 12:00

PC Close Date & Time

20 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

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

20 SEP 2020 18:55

PC Open Date & Time

20 SEP 2020 12:00

PC Close Date & Time

21 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

21 SEP 2020 17:21

PC Open Date & Time

21 SEP 2020 12:00

PC Close Date & Time

22 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

22 SEP 2020 17:35

PC Open Date & Time

22 SEP 2020 12:00

PC Close Date & Time

23 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

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

24 SEP 2020 06:17

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 11:27
PC Open Date & Time	17 SEP 2020 11:09
PC Close Date & Time	17 SEP 2020 13:39

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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

No ☒

Yes ☐

PC Time stamp	17 SEP 2020 15:46
PC Open Date & Time	17 SEP 2020 14:34
PC Close Date & Time	18 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

103 of 2333

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	18 SEP 2020 16:22
PC Open Date & Time	18 SEP 2020 12:00
PC Close Date & Time	19 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

105 of 2333

EAB) (1725)

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	19 SEP 2020 21:04
PC Open Date & Time	19 SEP 2020 12:00
PC Close Date & Time	20 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

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)

107 of 2333

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	20 SEP 2020 18:56
PC Open Date & Time	20 SEP 2020 12:00
PC Close Date & Time	21 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

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

109 of 2333

EAB) (1725)

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	21 SEP 2020 17:21
PC Open Date & Time	21 SEP 2020 12:00
PC Close Date & Time	22 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

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)

111 of 2333

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	22 SEP 2020 17:36
PC Open Date & Time	22 SEP 2020 12:00
PC Close Date & Time	23 SEP 2020 11:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

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 ☒

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 06:18
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 OCT 2020
Time of assessment (00:00-23:59)	11:00 (24 HR)
Vital Signs Date and Time (derived)	15 OCT 2020 11:00
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	103 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

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.

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

15 OCT 2020

Collection time (00:00-23:59)

11:10 (24 HR)

Collection date and time (derived)

15 OCT 2020 11:10

US3292236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:43

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	20 OCT 2020 05:33:28
Patient Cloud Open Date & Time	20 OCT 2020 00:01
Patient Cloud Close Date & Time	24 OCT 2020 23:59

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 71

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 OCT 2020 09:18:59

Patient Cloud Open Date & Time

27 OCT 2020 00:01

Patient Cloud Close Date & Time

31 OCT 2020 23:59

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 10:40:58

Patient Cloud Open Date & Time

03 NOV 2020 00:01

Patient Cloud Close Date & Time

07 NOV 2020 23:59

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

17 NOV 2020 12:58:31

Patient Cloud Open Date & Time

17 NOV 2020 00:01

Patient Cloud Close Date & Time

21 NOV 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	22 NOV 2020 09:47:24
Patient Cloud Open Date & Time	21 NOV 2020 00:01
Patient Cloud Close Date & Time	25 NOV 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 103

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 12:00:50

Patient Cloud Open Date & Time

28 NOV 2020 00:01

Patient Cloud Close Date & Time

02 DEC 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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	05 DEC 2020 13:37:13
Patient Cloud Open Date & Time	05 DEC 2020 00:01
Patient Cloud Close Date & Time	09 DEC 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

12 DEC 2020 06:06:17

Patient Cloud Open Date & Time

12 DEC 2020 00:01

Patient Cloud Close Date & Time

16 DEC 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 DEC 2020 12:13:33

Patient Cloud Open Date & Time

19 DEC 2020 00:01

Patient Cloud Close Date & Time

23 DEC 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 DEC 2020 12:01:43

Patient Cloud Open Date & Time

26 DEC 2020 00:01

Patient Cloud Close Date & Time

30 DEC 2020 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

04 JAN 2021 11:03:31

Patient Cloud Open Date & Time

02 JAN 2021 00:01

Patient Cloud Close Date & Time

06 JAN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

11 JAN 2021 10:16:42

Patient Cloud Open Date & Time

09 JAN 2021 00:01

Patient Cloud Close Date & Time

13 JAN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

16 JAN 2021 12:49:14

Patient Cloud Open Date & Time

16 JAN 2021 00:01

Patient Cloud Close Date & Time

20 JAN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

23 JAN 2021 06:32:24

Patient Cloud Open Date & Time

23 JAN 2021 00:01

Patient Cloud Close Date & Time

27 JAN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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	31 JAN 2021 14:21:56
Patient Cloud Open Date & Time	30 JAN 2021 00:01
Patient Cloud Close Date & Time	03 FEB 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

08 FEB 2021 08:32:16

Patient Cloud Open Date & Time

06 FEB 2021 00:01

Patient Cloud Close Date & Time

10 FEB 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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	15 FEB 2021 13:20:12
Patient Cloud Open Date & Time	13 FEB 2021 00:01
Patient Cloud Close Date & Time	17 FEB 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 FEB 2021 06:55:15

Patient Cloud Open Date & Time

20 FEB 2021 00:01

Patient Cloud Close Date & Time

24 FEB 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 MAR 2021 12:01:51

Patient Cloud Open Date & Time

27 FEB 2021 00:01

Patient Cloud Close Date & Time

03 MAR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

06 MAR 2021 08:10:24

Patient Cloud Open Date & Time

06 MAR 2021 00:01

Patient Cloud Close Date & Time

10 MAR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 MAR 2021 13:41:29

Patient Cloud Open Date & Time

13 MAR 2021 00:01

Patient Cloud Close Date & Time

17 MAR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 MAR 2021 07:27:33

Patient Cloud Open Date & Time

20 MAR 2021 00:01

Patient Cloud Close Date & Time

24 MAR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	28 MAR 2021 17:07:15
Patient Cloud Open Date & Time	27 MAR 2021 00:01
Patient Cloud Close Date & Time	31 MAR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 APR 2021 12:00:49

Patient Cloud Open Date & Time

03 APR 2021 00:01

Patient Cloud Close Date & Time

07 APR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 APR 2021 12:40:55

Patient Cloud Open Date & Time

10 APR 2021 00:01

Patient Cloud Close Date & Time

14 APR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

20 APR 2021 12:06:20

Patient Cloud Open Date & Time

17 APR 2021 00:01

Patient Cloud Close Date & Time

21 APR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

25 APR 2021 08:01:05

Patient Cloud Open Date & Time

24 APR 2021 00:01

Patient Cloud Close Date & Time

28 APR 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

03 MAY 2021 12:07:36

Patient Cloud Open Date & Time

01 MAY 2021 00:01

Patient Cloud Close Date & Time

05 MAY 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

[Patient Cloud Close Date & Time](#)

19 MAY 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

26 MAY 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

29 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

02 JUN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

05 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

12 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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="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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

26 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	03 JUL 2021 00:01
Patient Cloud Close Date & Time	07 JUL 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	10 JUL 2021 00:01
Patient Cloud Close Date & Time	14 JUL 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	17 JUL 2021 00:01
Patient Cloud Close Date & Time	21 JUL 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 355

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

07 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

11 AUG 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 <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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

14 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

18 AUG 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	21 AUG 2021 00:01
Patient Cloud Close Date & Time	25 AUG 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

28 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

01 SEP 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

08 SEP 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

11 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	18 SEP 2021 00:01
Patient Cloud Close Date & Time	22 SEP 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

25 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

29 SEP 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

[Patient Cloud Close Date & Time](#)

06 OCT 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

09 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

13 OCT 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

20 OCT 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

27 OCT 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

03 NOV 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

06 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

10 NOV 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

17 NOV 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

24 NOV 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

01 DEC 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

08 DEC 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

11 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

15 DEC 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	18 DEC 2021 00:01
Patient Cloud Close Date & Time	22 DEC 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	25 DEC 2021 00:01
Patient Cloud Close Date & Time	29 DEC 2021 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JAN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

[Patient Cloud Close Date & Time](#)

19 JAN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

[Patient Cloud Close Date & Time](#)

26 JAN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

05 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

09 FEB 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

12 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

16 FEB 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

19 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

23 FEB 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

26 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

05 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

12 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

19 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

23 MAR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

[Patient Cloud Close Date & Time](#)

30 MAR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

02 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	09 APR 2022 00:01
Patient Cloud Close Date & Time	13 APR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission	
Patient Cloud Open Date & Time	16 APR 2022 00:01
Patient Cloud Close Date & Time	20 APR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

27 APR 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 MAY 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

07 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

14 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

21 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

28 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

18 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JUL 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

[Patient Cloud Close Date & Time](#)

13 JUL 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 705

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

06 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission

Patient Cloud Open Date & Time	13 AUG 2022 00:01
--	-------------------

Patient Cloud Close Date & Time	17 AUG 2022 23:59
---	-------------------

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

17 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

Date and time of submission	
Patient Cloud Open Date & Time	01 OCT 2022 00:01
Patient Cloud Close Date & Time	05 OCT 2022 23:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

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

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

US3292236

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:28:29

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
Yes	Yes	01 MAR 2021 12:02:35

US3292236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 NOV 2020

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

Comments SAFETY CALL CONDUCTED 12
NOV 2020, BUT NO DATA WAS
If Contact Not Made, please provide Comments INPUT ON E-SOURCE

US3292236

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

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

Visit date (dd MMM yyyy)	17 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
------------	--------

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

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) _____

US3292236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

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.

US3292236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	17 MAR 2021
Collection time (00:00-23:59)	10:29 (24 HR)
Collection date and time (derived)	17 MAR 2021 10:29

US3292236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 22 Apr 2021 15:48:35

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted? Yes ☒ No ☐

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

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

Comments 3 ATTEMPTS NO ANSWER

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 22 Apr 2021 15:48:35

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292236

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:28:29

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"/>

US3292236

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:28:29

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3292236

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

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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

Visit date (dd MMM yyyy)	12 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
------------	---------------

US3292236

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

Date of updated informed consent (dd MMM yyyy)	12 JAN 2021
N/A - Subject Unblinded under Amendment 5 and Discontinued from Study	False
Was the participant unblinded?	Yes <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)	12 JAN 2021
Participant randomization assignment	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/>
Actual Dose 1	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Actual Dose 2	mRNA-1273 <input type="radio"/> Placebo <input checked="" type="radio"/> Not Administered <input type="radio"/>
Will participant receive mRNA-1273?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Placebo Only Flag	1
Continuing with mRNA-1273	1

US3292236

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

Form: Vital Signs - Dosing

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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

US3292236

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

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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)	12 JAN 2021
Time of assessment (00:00-23:59)	10:36 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 10:36
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	100 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	59 mmHg
Diastolic Blood Pressure units	MMHG

US3292236

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

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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)	12 JAN 2021
Time of assessment (00:00-23:59)	12:15 (24 HR)
Vital Signs Date and Time (derived)	12 JAN 2021 12:15
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	55 mmHg
Diastolic Blood Pressure units	MMHG

US3292236

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

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

12 JAN 2021

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

US3292236

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

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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) 12 JAN 2021

What was the treatment time? (00:00-23:59) 11:45 (24 HR)

Treatment Date and Time (derived) 12 JAN 2021 11:45

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

US3292236

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00-23:59)	10:40 (24 HR)
Collection date and time (derived)	12 JAN 2021 10:40

US3292236

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	12 JAN 2021
Collection time (00:00 - 23:59)	11:05
Collection Date and Time (derived)	12 JAN 2021 11:05

US3292236

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

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: OL-D29 (1)

Form: Visit Date

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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	OLD29

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 03 Mar 2021 14:15:54

Generated On: 09 Jun 2021 16:28:29

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)	10:16 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 10:16
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)	74 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	106 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	53 mmHg
Diastolic Blood Pressure units	MMHG

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 03 Mar 2021 14:15:54

Generated On: 09 Jun 2021 16:28:29

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)	9 FEB 2021
Time of assessment (00:00-23:59)	11:40 (24 HR)
Vital Signs Date and Time (derived)	9 FEB 2021 11:40
Temperature (xxx.x)	37.5 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	67 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	105 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3292236

Folder: OL-D29 (1)

Form: Physical Examination

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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.

US3292236

Folder: OL-D29 (1)

Form: Exposure

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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) 11:08 (24 HR)

Treatment Date and Time (derived) 9 FEB 2021 11:08

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

US3292236

Folder: OL-D29 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292236

Folder: Safety Call OL-D36 (1)

Form: Continuing

Data signed: (b) (4) 22 Feb 2021 21:15:38

Generated On: 09 Jun 2021 16:28:29

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292236

Folder: OL-D57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	11 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	OLD57

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

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) _____

US3292236

Folder: OL-D57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

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.

US3292236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 MAR 2021
Collection time (00:00-23:59)	08:48 (24 HR)
Collection date and time (derived)	11 MAR 2021 08:48

US3292236

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

AEID	USA-US072-2020-MRNA-1273-P30 1000001
Adverse event	FIBROMUSCULAR DYSPLASIA
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)	4 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	5 SEP 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input 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)	4 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	5 SEP 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2333

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

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	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	

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

THIS REPORT IS FOLLOWING
PATIENT'S INITIAL REPORT TO
STAFF ON THE MORNING OF
09SEP2020. PT RECEIVED FIRST
IP INJECTION ON 20AUG2020.

ON 21ST, PT HAD
APPOINTMENT WITH DOCTOR
FOR MIGRAINES. DOCTOR
PRESCRIBED AIMOVIG, WHICH
PT STARTED IMMEDIATELY.

ON 03SEP, PT WAS "NOT
FEELING NORMAL". SHE
COULD NOT DESCRIBE HER
SYMPTOMS, SIMPLY STATING

SHE WAS NOT FEELING
NORMAL. ON 04SEP PT STATES
SHE WOKE UP TO THE ROOM
SPINNING, SHE WAS

EXPERIENCING NAUSEA, AND
CALLED AN AMBULANCE.

WHILE IN THE AMBULANCE,
EMT GAVE PT SOMETHING FOR
NAUSEA, THOUGH PT CANNOT
RECALL WHAT IT WAS. WHILE

IN THE ER, PT STATES
DOCTORS DID "EVERY TEST
KNOWN TO MAN", BUT COULD
NOT FIND ANYTHING

ABNORMAL. DOCTORS
DECIDED TO CONDUCT MRI
WITH CONTRAST. ACCORDING
TO PATIENT, SHE WAS TOLD

BY HER DOCTOR THAT SHE
HAD "POSSIBLE
FIBROMUSCULAR DYSPLASIA".

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

AT THIS TIME, PT WAS UNABLE
TO PROVIDE ANY FURTHER
INFORMATION. WE WILL
REQUEST MEDICAL RECORDS
FROM HOSPITAL ASAP.
UPDATE: DISCHARGE
SUMMARY SENT TO SAFETY
24SEP2020. STATES "MRI
FINDINGS OF BEADING IN
DISTAL CERVICAL ARTERIES
SUGGESTED POSSIBLE
FIBROMUSCULAR DYSPLASIA."
D/C SUMMARY ALSO STATES
THAT PATIENT IS TO FOLLOW
UP WITH NEUROLOGIST TO
DISCUSS THESE FINDINGS. NO
FURTHER INFORMATION OR
LAB RESULTS GIVEN. COVID
TESTING NOT MENTIONED.
PLEASE REVIEW REPORT.

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

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

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

PRODUCTION RELEASE (v12.003

357 of 2333

EAB) (1725)

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

358 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

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

Yes ☒

No ☐

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

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication OSTEOPENIA

Dose per administration 1800

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)

360 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2000	
Start date completely unknown	False	
Ongoing?	Yes <input 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"/>	

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication MAGNESIUM

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

362 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	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 2015	
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"/>

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication POTASSIUM

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 198

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)

364 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
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"/>

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication COENZYME Q10

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

366 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2017	
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"/>

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication TURMERIC

Prophylaxis Yes ☒
No ☐

Indication NUTRITIONAL SUPPLEMENT

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

368 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	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 2015	
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"/>

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication SUMATRIPTAN

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

370 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	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 1985
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"/>

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication FISH OIL

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

372 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
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"/>

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication AIMOVIG

Prophylaxis Yes ☐
No ☒

Indication MIGRAINE HEADACHES

Dose per administration 70

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)

374 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 21 AUG 2020		
Was this medication taken for solicited event?	Yes	<input checked="" 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"/>

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication MECLIZINE

Prophylaxis Yes ☐
No ☒

Indication VERTIGO

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

376 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	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)		04 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		05 SEP 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

Name of Medication BOTOX

Prophylaxis Yes ☒
No ☐

Indication COSMETIC FACIAL INJECTION

Dose per administration 1

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

If dose unit is Other, specify INJECTION

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)

378 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 22 Apr 2021 15:48:31

Generated On: 09 Jun 2021 16:28:29

	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)	UN APR 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		UN APR 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"/>

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Feb 2021 21:15:37

Generated On: 09 Jun 2021 16:28:29

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
4 SEP 2020	BRAIN MRI	Diagnostic	
4 SEP 2020	BRAIN MRA	Diagnostic	

US3292236

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:28:29

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

US3292236

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:28:29

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 ☐

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	10/SEP/2020 13:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	22/SEP/2020 10:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	25/SEP/2020 16:49
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	14/OCT/2020 13:36
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.	True

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	05/NOV/2020 15:03
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	06/NOV/2020 14:31
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	25/NOV/2020 13:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	17/FEB/2021 16:25
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

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Data signed: (b) (4) 16 Apr 2021 14:18:49

Generated On: 09 Jun 2021 16:28:29

SAEID	USA-US072-2020-MRNA-1273-P301000001
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)	9
Date of submission (Pre-filled from custom function)	11/MAR/2021 11:30
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

US3292236 (Prod: Clinical Trials of Texas, Inc)

US3292236

Form: Participant Creation

Generated On: 09 Jun 2021 16:28:29

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:19:05
User entered 'US3292236'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:54:53

US3292236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:08
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:20:03

US3292236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:08
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:54:54

US3292236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:08
User entered 'Clinic (Clinic)'		21 Aug 2020 13:20:03

US3292236

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'SCRN'	System	21 Aug 2020 13:20:03

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:27
User entered (b) (6) 1940'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:54:55

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:27
User entered '80'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'YEARS'	System	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '80'	System	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:27
User entered 'Female (F)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	21 Sep 2020 22:06:57
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered 'l'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:27
User entered empty.		21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:28:29

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:44:27
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:20:30

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:44:53
User entered '20 Aug 2020'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Aug 2020'	System	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2020'	System	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:53
User entered 'Amendment 2 (2)'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:53
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:53
User entered empty.	Nathan Cortez (b) (4)	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:53
User entered empty.	Nathan Cortez (b) (4)	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:53
User entered 'No (N)'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:14

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:44:53
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 13:54:54

US3292236

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:28:29

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'l'	System	20 Aug 2020 15:25:21

US3292236

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:45:02
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:21

US3292236

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:28:29

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Query 'Nausea was listed on Discharge Summary. Please confirm and consider updating MH.' canceled (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Oct 2020 19:54:33
Query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating MH.' canceled (Site from CRA).	(b) (4), (b) (6)	23 Oct 2020 19:54:31
User opened query 'Nausea was listed on Discharge Summary. Please confirm and consider updating MH.' (Site from CRA).		21 Oct 2020 18:36:29
User opened query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating MH.' (Site from CRA).		21 Oct 2020 18:35:46
DataPoint Verified.		01 Oct 2020 17:45:14
User entered 'Yes (Y)'		21 Aug 2020 13:20:47

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:25:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:25:24
Data point term sent to Coder	System	21 Aug 2020 13:24:07
User entered 'Seasonal allergies'	(b) (4), (b) (6)	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 1972'		21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1972'	System	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1972'	System	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:23:52

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Food allergy, LLT: Soy allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 04:51:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Aug 2020 04:51:47
Data point term sent to Coder	System	21 Aug 2020 13:25:08
User entered 'Allergies to soy'	(b) (4), (b) (6)	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1987'	(b) (4), (b) (6)	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1987'	System	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1987'	System	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:24:12

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 22:20:39
		01 Oct 2020 17:46:39
Query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'related to uterine fibroids' (Site from DM).		21 Sep 2020 19:34:36
User opened query 'Per DM CLR: Please review this Condition and please note that this information is not reflected on the Childbearing Potential eCRF page. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).		21 Sep 2020 13:01:31
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Uterine therapeutic procedures, PT: Hysterectomy, LLT: Hysterectomy - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 13:25:25
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 13:25:25
Data point term sent to Coder	System	21 Aug 2020 13:25:08
User entered 'Hysterectomy'	(b) (4), (b) (6)	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1979'	(b) (4), (b) (6)	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 1979'		21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1979'	System	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1979'	System	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1979'	System	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1979'	System	21 Aug 2020 13:24:42

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Please confirm reason for hospitalization. Per source, indication was pneumonia.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:30:34
		21 Oct 2020 17:33:18
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 15:42:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	05 Oct 2020 15:42:23
Data point term sent to Coder	System	05 Oct 2020 15:41:56
Query 'Please confirm reason for hospitalization. Per source, indication was pneumonia.' answered with 'updated' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	05 Oct 2020 15:41:44
		05 Oct 2020 15:41:37
Coding entries removed.		05 Oct 2020 15:41:37
User entered 'HOSPITALIZATION - Pneumonia' reason for change: Data Entry Error		05 Oct 2020 15:41:37
User opened query 'Please confirm reason for hospitalization. Per source, indication was pneumonia.' (Site from CRA). DataPoint Verified.		01 Oct 2020 17:50:29
		01 Oct 2020 17:46:39
User coded data point as SOC: Psychiatric disorders, HLGT: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\23.0.	Coder Import (b) (4)	22 Aug 2020 08:27:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Aug 2020 08:27:15
Data point term sent to Coder	System	21 Aug 2020 13:27:12
User entered 'Hospitalization - depression'	(b) (4), (b) (6)	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1990'	(b) (4), (b) (6)	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 1990'		21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1990'	System	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1990'	System	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1990'	System	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1990'	System	21 Aug 2020 13:26:51

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Lower respiratory tract and lung infections, PT: Pneumonia, LLT: Pneumonia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 08:27:15
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 08:27:15
Data point term sent to Coder	System	21 Aug 2020 13:28:18
User entered 'Hospitalization - pneumonia'	(b) (4), (b) (6)	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 2019'		21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2019'	System	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2019'	System	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2019'	System	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2019'	System	21 Aug 2020 13:27:46

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\23.0.	Coder Import (b) (4)	24 Oct 2020 20:29:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Oct 2020 20:29:33
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Lens therapeutic procedures, PT: Cataract operation, LLT: Bilateral cataract extraction - version MedDRA\23.0.	Coder Import (b) (4)	22 Aug 2020 08:03:10
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Aug 2020 08:03:10
Data point term sent to Coder	System	21 Aug 2020 13:33:29
User entered 'Cataract removal OU - bilateral'	(b) (4), (b) (6)	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 2016'	(b) (4), (b) (6)	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'No (N)'		21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 2016'	(b) (4), (b) (6)	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2016'	System	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2016'	System	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2016'	System	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2016'	System	21 Aug 2020 13:32:51

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal haemorrhages NEC, HLT: Non-site specific gastrointestinal haemorrhages, PT: Upper gastrointestinal haemorrhage, LLT: Upper gastrointestinal bleeding - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:38:12
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:38:12
Data point term sent to Coder	System	21 Aug 2020 13:34:30
User entered 'Upper GI bleed'	(b) (4), (b) (6)	21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1986'	(b) (4), (b) (6)	21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered '0'		21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1986'	(b) (4), (b) (6)	21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered '0'		21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1986'	System	21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1986'	System	21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1986'	System	21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1986'	System	21 Aug 2020 13:33:42

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Hearing disorders, HLT: Hearing losses, PT: Deafness bilateral, LLT: Hearing loss bilateral - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:35:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:35:17
Data point term sent to Coder	System	21 Aug 2020 13:34:32
User entered 'Bilateral hearing loss'	(b) (4), (b) (6)	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1990'	(b) (4), (b) (6)	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1990'	System	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1990'	System	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:34:17

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per DM CLR: Please review the stop date of this MH as there was a noted procedure of MH #6 CATARACT REMOVAL OU - BILATERAL done last UN UNK 2016 that matches this condition. Note that associated conditions usuall resolve within the timeframe of the procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 15:58:46
		01 Oct 2020 17:46:39
Query 'Per DM CLR: Please review the stop date of this MH as there was a noted procedure of MH #6 CATARACT REMOVAL OU - BILATERAL done last UN UNK 2016 that matches this condition. Note that associated conditions usually resolve within the timeframe of the procedure. Please correct dates or provide explanation for the Med History dates. ' answered with 'updated' (Site from DM).		21 Sep 2020 19:35:32
User opened query 'Per DM CLR: Please review the stop date of this MH as there was a noted procedure of MH #6 CATARACT REMOVAL OU - BILATERAL done last UN UNK 2016 that matches this condition. Note that associated conditions usually resolve within the timeframe of the procedure. Please correct dates or provide explanation for the Med History dates. ' (Site from DM).		21 Sep 2020 13:02:23
User coded data point as SOC: Eye disorders, HLGT: Coder Import (b) (4) Anterior eye structural change, deposit and degeneration, HLT: Cataract conditions, PT: Cataract, LLT: Bilateral cataracts - version MedDRA\23.0.	(b) (4)	21 Aug 2020 13:36:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Aug 2020 13:36:19
Data point term sent to Coder	System	21 Aug 2020 13:35:32
User entered 'Cataracts OU'	(b) (4), (b) (6)	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1986'	(b) (4), (b) (6)	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'UN UNK 2016' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Sep 2020 19:35:26
User entered 'un UNK 1986'		21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1986'	System	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1986'	System	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2016'	System	21 Sep 2020 19:35:26
User entered 'Jan 1986'	System	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2016'	System	21 Sep 2020 19:35:26
User entered '1986'	System	21 Aug 2020 13:34:50

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Gastrointestinal disorders, HLG: Gastrointestinal ulceration and perforation, HLT: Gastric ulcers and perforation, PT: Gastric ulcer, LLT: Stomach ulcer - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:36:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:36:20
Data point term sent to Coder	System	21 Aug 2020 13:35:35
User entered 'Stomach ulcer'	(b) (4), (b) (6)	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 1986'		21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1986'	(b) (4), (b) (6)	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1986'	System	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1986'	System	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1986'	System	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1986'	System	21 Aug 2020 13:35:13

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:37:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:37:32
Data point term sent to Coder	System	21 Aug 2020 13:36:36
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 2015'		21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'Yes (Y)'		21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2015'	System	21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2015'	System	21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:35:42

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Miscellaneous and site unspecified neoplasms malignant and unspecified, HLT: Neoplasms malignant site unspecified NEC, PT: Squamous cell carcinoma, LLT: Squamous cell carcinoma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:31:20
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Aug 2020 09:31:20
Data point term sent to Coder	System	21 Aug 2020 13:37:42
User entered 'Squamous cell cancer - RLE'	(b) (4), (b) (6)	21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 2000'		21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 2000'		21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2000'	System	21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2000'	System	21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2000'	System	21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2000'	System	21 Aug 2020 13:37:34

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Metabolic bone disorders, PT: Osteopenia, LLT: Osteopenia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:40:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:40:23
Data point term sent to Coder	System	21 Aug 2020 13:38:42
User entered 'Osteopenia'	(b) (4), (b) (6)	21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 2000'		21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered '0'		21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 2000'	System	21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '2000'	System	21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:37:55

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Migraine headaches, PT: Migraine, LLT: Migraine headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:40:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:40:24
Data point term sent to Coder	System	21 Aug 2020 13:38:43
User entered 'Migraine headaches'	(b) (4), (b) (6)	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1987'	(b) (4), (b) (6)	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered empty.		21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1987'	System	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1987'	System	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered empty.	System	21 Aug 2020 13:38:24

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Reproductive neoplasms female benign, HLT: Uterine neoplasms benign, PT: Uterine leiomyoma, LLT: Uterine fibroids - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:40:24
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:40:24
Data point term sent to Coder	System	21 Aug 2020 13:39:43
User entered 'Uterine fibroids'	(b) (4), (b) (6)	21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'un UNK 1979'	(b) (4), (b) (6)	21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 17:46:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered 'un UNK 1979'		21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 17:46:39
User entered '0'		21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1979'	System	21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1979'	System	21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'Jan 1979'	System	21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '1979'	System	21 Aug 2020 13:38:56

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:02:45
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:02:45
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:02:45
User entered '08:36'	(b) (4), (b) (6)	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered '20 Aug 2020 08:36'	System	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:02:45
User entered '171.0' cm		21 Aug 2020 13:40:25
DataPoint set to visible.	System	20 Aug 2020 15:25:21

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:02:45
User entered '59.7' kg		21 Aug 2020 13:40:25
DataPoint set to visible.	System	20 Aug 2020 15:25:21

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
Amendment Manager: User entered '20.41654'	System	17 Sep 2020 00:15:42
User entered '20.4'	System	21 Aug 2020 13:40:25
DataPoint set to visible.	System	20 Aug 2020 15:25:21

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'kg/m2'	System	21 Aug 2020 13:40:25
DataPoint set to visible.	System	20 Aug 2020 15:25:21

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:02:45
User closed query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	29 Sep 2020 14:08:50
Query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4)	22 Sep 2020 18:20:31
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	22 Sep 2020 18:20:26
User opened query 'Per CDM: Response noted; however per CCGs pages 15-16, ND should be recorded for TEMPERATURE, PULSE, RESPIRATORY RATE, SYSTOLIC BP, and DIASTOLIC BP. Please update accordingly.' (Site from DM).	(b) (4), (b) (6)	24 Aug 2020 19:04:35
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 19:04:26
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).		21 Aug 2020 13:42:57
User opened query 'Data is required. Please provide.' (Site from System).	System	21 Aug 2020 13:40:25
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:02:45
User entered empty.		21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:02:45
User entered empty.		21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4)	28 Oct 2020 10:51:40
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:35:35
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'updated' (Site from DM).		07 Oct 2020 17:59:57
DataPoint Un-verified.		07 Oct 2020 17:59:49
User entered missing code ND - Not Done; reason for change Data Entry Error		07 Oct 2020 17:59:49
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).		07 Oct 2020 12:43:23
DataPoint Verified.		01 Oct 2020 18:02:45
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 19:04:37
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).		21 Aug 2020 13:43:12
User opened query 'Data is required. Please provide.' System		21 Aug 2020 13:40:25
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'bpm'	System	07 Oct 2020 17:59:49
User entered empty.	System	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:51:57
DataPoint Verified.		21 Oct 2020 17:35:35
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'updated' (Site from DM).		07 Oct 2020 18:00:03
DataPoint Un-verified.		07 Oct 2020 17:59:49
User entered missing code ND - Not Done; reason for change Data Entry Error		07 Oct 2020 17:59:49
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).		07 Oct 2020 12:43:30
DataPoint Verified.		01 Oct 2020 18:02:45
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 19:04:39
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).		21 Aug 2020 13:43:16
User opened query 'Data is required. Please provide.' System		21 Aug 2020 13:40:25
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'breaths/min'	System	07 Oct 2020 17:59:49
User entered empty.	System	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 10:52:20
DataPoint Verified.		21 Oct 2020 17:35:35
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'updated' (Site from DM).		07 Oct 2020 18:00:09
DataPoint Un-verified.		07 Oct 2020 17:59:49
User entered missing code ND - Not Done; reason for change Data Entry Error		07 Oct 2020 17:59:49
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).		07 Oct 2020 12:43:36
DataPoint Verified.		01 Oct 2020 18:02:45
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 19:04:40
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).		21 Aug 2020 13:43:20
User opened query 'Data is required. Please provide.' System		21 Aug 2020 13:40:25
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'mmHg'	System	07 Oct 2020 17:59:49
User entered empty.	System	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).	(b) (4)	28 Oct 2020 10:52:41
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 17:35:35
Query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' answered with 'updated' (Site from DM).		07 Oct 2020 18:00:14
DataPoint Un-verified.		07 Oct 2020 17:59:49
User entered missing code ND - Not Done; reason for change Data Entry Error		07 Oct 2020 17:59:49
User opened query 'Per CDM: As per CCG, "ND" to be updated in the text field. ' (Site from DM).		07 Oct 2020 12:43:45
DataPoint Verified.		01 Oct 2020 18:02:45
User closed query 'Data is required. Please provide.' (Site from System).		24 Aug 2020 19:04:42
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).		21 Aug 2020 13:43:24
User opened query 'Data is required. Please provide.' System		21 Aug 2020 13:40:25
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User entered 'mmHg'	System	07 Oct 2020 17:59:49
User entered empty.	System	21 Aug 2020 13:40:25

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34

US3292236

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34

US3292236

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:44
User entered 'Yes (Y)'		21 Aug 2020 13:43:55

US3292236

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:03:44
User entered '20 Aug 2020'		21 Aug 2020 13:43:55

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:56
User entered '20 Aug 2020'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:24:02

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:56
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:24:02

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:29

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:56
User entered 'Surgically sterile (SURGICALLY STERILE)'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:24:02

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:29

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:56
User entered empty.	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:24:02

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:56
User entered 'un UNK 1979'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:24:02

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:29

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:56
User entered '0'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:24:02

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:03:56
User entered empty.	Kevin Martinez (b) (4)	21 Sep 2020 22:24:02

US3292236

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:28:29

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:03:56
User entered '0'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:24:02

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:04:29
User entered 'No (N)'		21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:04:29
User entered 'No (N)'		21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

[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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:04:29
User entered 'No (N)'		21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:04:29
User entered 'No (N)'		21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:04:29
User entered 'No (N)'		21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:04:29
User entered 'No (N)'		21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:04:29
User entered '0'		21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:04:29
User entered 'l'		21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:28:29

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:38:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:04:29
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:44:39

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:05:16
User entered 'Yes (Y)'		21 Aug 2020 13:53:17

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:05:16
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 13:53:17

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:05:16
User entered 'Clinic (Clinic)'	(b) (4), (b) (6)	21 Aug 2020 13:53:17

US3292236

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'VISIT1'	System	21 Aug 2020 13:53:17

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:10
User entered '20 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:49:27

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:10
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 05:49:13
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 05:49:13
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	20 Aug 2020 14:49:27
User entered '187235' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:49:27

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:10
User entered '>=65 years (3)'	RWS_ENDPOINT ENDPOINT (b) (4)	20 Aug 2020 14:49:27

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:10
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:54:44

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:10
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:54:44

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:10
User entered 'No (N)'		21 Aug 2020 13:54:44

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:10
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:54:44

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:10
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:54:44

US3292236

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:28:29

[Human Immunodeficiency Virus \(HIV\) infection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:10
User entered 'No (N)'	Kevin Martinez (b) (4)	21 Sep 2020 22:24:15
Amendment Manager: DataPoint set to visible.	(b) (4)	19 Sep 2020 10:36:42
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 01:42:06

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered missing code ND - Not Done.		21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered missing code ND - Not Done.		21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered 'Yes (Y)'		21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered '09:14'		21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered '20 Aug 2020 09:14'	System	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered '36.8' C		21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered '72'		21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'bpm'	System	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered '16'	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'breaths/min'	System	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered '115'		21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'mmHg'	System	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:44
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	02 Nov 2020 15:22:23
		01 Oct 2020 18:07:52
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'normal per PI.' (Site from System).	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:25:03
Amendment Manager: User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	17 Sep 2020 00:15:42
User entered '59'	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'mmHg'	System	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered missing code ND - Not Done.	(b) (4), (b) (6)	21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered missing code ND - Not Done.		21 Aug 2020 14:02:26

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User accepted default value 'Post-Dose (POSTDOSE)'		21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered 'Yes (Y)'		21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered '10:47'	(b) (4), (b) (6)	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered '20 Aug 2020 10:47'	System	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered '36.4' C		21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered 'Oral (Oral)'	(b) (4), (b) (6)	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered '62'		21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'bpm'	System	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered '20'	(b) (4), (b) (6)	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'breaths/min'	System	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:07:52
User entered '114'	(b) (4), (b) (6)	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'mmHg'	System	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:07:52
User entered '60'		21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'mmHg'	System	21 Aug 2020 14:03:17

US3292236

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:09:15
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:04:29

US3292236

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:09:15
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:04:29

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:09:22
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:09:22
User entered empty.	Nathan Cortez (b) (4)	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:09:22
User entered empty.	Nathan Cortez (b) (4)	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'MRNA-1273 OR PLACEBO'	System	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:09:22
User entered '20 Aug 2020'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:09:22
User entered '10:14'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered '20 Aug 2020 10:14'	System	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:09:22
User entered 'Left Arm (LEFT ARM)'	Nathan Cortez (b) (4)	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
DataPoint Verified.		01 Oct 2020 18:09:22
User entered 'ONCE'	System	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'INTRAMUSCULAR'	System	20 Aug 2020 15:25:41

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:10:41
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 14:03:42

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:10:41
User entered '20 Aug 2020'		21 Aug 2020 14:03:42

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	01 Oct 2020 18:10:41
User entered '09:37'	(b) (4), (b) (6)	21 Aug 2020 14:03:42

US3292236

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered '20 Aug 2020 09:37'	System	21 Aug 2020 14:03:42

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:11:04
User entered '20 Aug 2020'	(b) (4), (b) (6)	21 Aug 2020 14:04:04

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		21 Aug 2020 14:04:04

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:11:04
User entered 'Yes (Y)'		21 Aug 2020 14:04:04

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:11:04
User entered '09:27'	(b) (4), (b) (6)	21 Aug 2020 14:04:04

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered '20 Aug 2020 09:27'	System	21 Aug 2020 14:04:04

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	21 Aug 2020 14:04:11

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:11:04
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 14:04:11

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 18:11:04
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 14:04:11

US3292236

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered empty.	System	21 Aug 2020 14:04:11

US3292236

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:11:17
User entered 'Yes (Y)'		21 Aug 2020 14:04:17

US3292236

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'I'	System	21 Aug 2020 14:04:17

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '832e1cb4-44f0-4ffd-bfa2-3537c1d043f2'	System	20 Aug 2020 15:59:48
User entered 'Yes (Y)'	System	20 Aug 2020 15:59:48

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '832e1cb4-44f0-4ffd-bfa2-3537c1d043f2' User entered '97.5'	System	20 Aug 2020 15:59:48
	System	20 Aug 2020 15:59:48

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:26', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '832e1cb4-44f0-4ffd-bfa2-3537c1d043f2'	System	20 Aug 2020 15:59:48
User entered 'No (N)'	System	20 Aug 2020 15:59:48

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '832e1cb4-44f0-4ffd-bfa2-3537c1d043f2' User entered '20 Aug 2020 10:59'	System	20 Aug 2020 15:59:48
	System	20 Aug 2020 15:59:48

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 10:34'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 13:04'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:26:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '28d7d1f6-f9eb-4005-abdc-f287a0a02101' User entered 'Yes (Y)'	System	20 Aug 2020 23:27:37
	System	20 Aug 2020 23:27:37

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:26:54', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '28d7d1f6-f9eb-4005-abdc-f287a0a02101' User entered '97.3'	System	20 Aug 2020 23:27:37
	System	20 Aug 2020 23:27:37

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:27:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '28d7d1f6-f9eb-4005-abdc-f287a0a02101'	System	20 Aug 2020 23:27:37
User entered 'No (N)'	System	20 Aug 2020 23:27:37

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:27:34', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '28d7d1f6-f9eb-4005-abdc-f287a0a02101'	System	20 Aug 2020 23:27:37
User entered '20 Aug 2020 18:27'	System	20 Aug 2020 23:27:37

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 13:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 2'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:03:29', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5dcfa22-5dd9-41e5-824a-54dc4d338406' User entered 'Yes (Y)'	System	21 Aug 2020 20:04:49
	System	21 Aug 2020 20:04:49

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:04:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5dcfa22-5dd9-41e5-824a-54dc4d338406' User entered '96.7'	System	21 Aug 2020 20:04:49
	System	21 Aug 2020 20:04:49

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:04:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5dcfa22-5dd9-41e5-824a-54dc4d338406'	System	21 Aug 2020 20:04:49
User entered 'No (N)'	System	21 Aug 2020 20:04:49

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:04:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5dcfa22-5dd9-41e5-824a-54dc4d338406' User entered '21 Aug 2020 15:04'	System	21 Aug 2020 20:04:49
	System	21 Aug 2020 20:04:49

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 3'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:02:17', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '160a7b22-0be5-42fd-9fc4-6ee13899f23b' User entered 'Yes (Y)'	System	22 Aug 2020 23:03:00
	System	22 Aug 2020 23:03:00

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:02:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '160a7b22-0be5-42fd-9fc4-6ee13899f23b' User entered '97.2'	System	22 Aug 2020 23:03:00
	System	22 Aug 2020 23:03:00

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:02:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '160a7b22-0be5-42fd-9fc4-6ee13899f23b' User entered 'No (N)'	System	22 Aug 2020 23:03:00
	System	22 Aug 2020 23:03:00

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:02:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '160a7b22-0be5-42fd-9fc4-6ee13899f23b' User entered '22 Aug 2020 18:02'	System	22 Aug 2020 23:03:00
	System	22 Aug 2020 23:03:00

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 4'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:04:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5b9ce84b-9b65-4f88-b471-ed0a1f5e8e0e' User entered 'Yes (Y)'	System	23 Aug 2020 23:05:38
	System	23 Aug 2020 23:05:38

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5b9ce84b-9b65-4f88-b471-ed0a1f5e8e0e' User entered '97.0'	System	23 Aug 2020 23:05:38
	System	23 Aug 2020 23:05:38

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5b9ce84b-9b65-4f88-b471-ed0a1f5e8e0e' User entered 'No (N)'	System	23 Aug 2020 23:05:38
	System	23 Aug 2020 23:05:38

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:32', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5b9ce84b-9b65-4f88-b471-ed0a1f5e8e0e' User entered '23 Aug 2020 18:05'	System	23 Aug 2020 23:05:38
	System	23 Aug 2020 23:05:38

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 5'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:28:17', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7c33810c-8d35-4a5b-80f9-97cb4542314e' User entered 'Yes (Y)'	System	25 Aug 2020 00:29:24
	System	25 Aug 2020 00:29:24

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7c33810c-8d35-4a5b-80f9-97cb4542314e' User entered '97.3'	System	25 Aug 2020 00:29:24
	System	25 Aug 2020 00:29:24

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7c33810c-8d35-4a5b-80f9-97cb4542314e' User entered 'No (N)'	System	25 Aug 2020 00:29:24
	System	25 Aug 2020 00:29:24

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7c33810c-8d35-4a5b-80f9-97cb4542314e' User entered '24 Aug 2020 19:29'	System	25 Aug 2020 00:29:24
	System	25 Aug 2020 00:29:24

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 6'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:25:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4e7339af-7723-487a-983e-3d43b5aebf56'	System	25 Aug 2020 22:26:28
User entered 'Yes (Y)'	System	25 Aug 2020 22:26:28

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4e7339af-7723-487a-983e-3d43b5aebf56' User entered '97.2'	System	25 Aug 2020 22:26:28
	System	25 Aug 2020 22:26:28

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4e7339af-7723-487a-983e-3d43b5aebf56'	System	25 Aug 2020 22:26:28
User entered 'No (N)'	System	25 Aug 2020 22:26:28

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4e7339af-7723-487a-983e-3d43b5aebf56'	System	25 Aug 2020 22:26:28
User entered '25 Aug 2020 17:26'	System	25 Aug 2020 22:26:28

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 7'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:21', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9fd212af-e9de-4b70-afab-e400224a41fb' User entered 'Yes (Y)'	System	26 Aug 2020 23:19:53
	System	26 Aug 2020 23:19:53

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:34', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9fd212af-e9de-4b70-afab-e400224a41fb' User entered '97.2'	System	26 Aug 2020 23:19:53
	System	26 Aug 2020 23:19:53

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:39', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9fd212af-e9de-4b70-afab-e400224a41fb' User entered 'No (N)'	System	26 Aug 2020 23:19:53
	System	26 Aug 2020 23:19:53

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9fd212af-e9de-4b70-afab-e400224a41fb' User entered '26 Aug 2020 18:19'	System	26 Aug 2020 23:19:53
	System	26 Aug 2020 23:19:53

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T10:59:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2'	System	20 Aug 2020 16:00:27
User entered 'None (1)'	System	20 Aug 2020 16:00:27

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2'	System	20 Aug 2020 16:00:27
User entered 'No (N)'	System	20 Aug 2020 16:00:27

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2'	System	20 Aug 2020 16:00:27
User entered 'No (N)'	System	20 Aug 2020 16:00:27

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2'	System	20 Aug 2020 16:00:27
User entered 'None (1)'	System	20 Aug 2020 16:00:27

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '898b506a-7565-454a-9807-8babf10d4ee2' User entered '20 Aug 2020 11:00'	System	20 Aug 2020 16:00:27
	System	20 Aug 2020 16:00:27

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 10:34'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 13:04'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' User entered 'None (1)'	System	20 Aug 2020 23:29:01
	System	20 Aug 2020 23:29:01

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' User entered 'No (N)'	System	20 Aug 2020 23:29:01
	System	20 Aug 2020 23:29:01

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' User entered 'No (N)'	System	20 Aug 2020 23:29:01
	System	20 Aug 2020 23:29:01

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' User entered 'None (1)'	System	20 Aug 2020 23:29:01
	System	20 Aug 2020 23:29:01

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:28:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '57641dc1-ecef-4b7b-a69b-a9bc5386980c' User entered '20 Aug 2020 18:28'	System	20 Aug 2020 23:29:01
	System	20 Aug 2020 23:29:01

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 13:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 2'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:02:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' User entered 'None (1)'	System	21 Aug 2020 20:03:10
	System	21 Aug 2020 20:03:10

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:02:42', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' User entered 'No (N)'	System	21 Aug 2020 20:03:10
	System	21 Aug 2020 20:03:10

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:02:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' User entered 'No (N)'	System	21 Aug 2020 20:03:10
	System	21 Aug 2020 20:03:10

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:02:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' User entered 'None (1)'	System	21 Aug 2020 20:03:10
	System	21 Aug 2020 20:03:10

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:03:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '507a995e-ac48-4436-945a-2f9d1e867956' User entered '21 Aug 2020 15:03'	System	21 Aug 2020 20:03:10
	System	21 Aug 2020 20:03:10

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 3'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' User entered 'None (1)'	System	22 Aug 2020 23:03:49
	System	22 Aug 2020 23:03:49

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:10', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' User entered 'No (N)'	System	22 Aug 2020 23:03:49
	System	22 Aug 2020 23:03:49

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' User entered 'No (N)'	System	22 Aug 2020 23:03:49
	System	22 Aug 2020 23:03:49

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' User entered 'None (1)'	System	22 Aug 2020 23:03:49
	System	22 Aug 2020 23:03:49

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd31fa9c4-1269-470a-9a3f-6dae1fbd1ba9' User entered '22 Aug 2020 18:03'	System	22 Aug 2020 23:03:49
	System	22 Aug 2020 23:03:49

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 4'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6'	System	23 Aug 2020 23:06:07
User entered 'None (1)'	System	23 Aug 2020 23:06:07

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6' User entered 'No (N)'	System	23 Aug 2020 23:06:07
	System	23 Aug 2020 23:06:07

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6' User entered 'No (N)'	System	23 Aug 2020 23:06:07
	System	23 Aug 2020 23:06:07

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:05:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6'	System	23 Aug 2020 23:06:07
User entered 'None (1)'	System	23 Aug 2020 23:06:07

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a8f6960-c151-40b4-b10b-46fa53ba2fa6'	System	23 Aug 2020 23:06:07
User entered '23 Aug 2020 18:06'	System	23 Aug 2020 23:06:07

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 5'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2ceb9ec5ea22'	System	25 Aug 2020 00:29:59
User entered 'None (1)'	System	25 Aug 2020 00:29:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:35', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2ceb9ec5ea22'	System	25 Aug 2020 00:29:59
User entered 'No (N)'	System	25 Aug 2020 00:29:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2ceb9ec5ea22'	System	25 Aug 2020 00:29:59
User entered 'No (N)'	System	25 Aug 2020 00:29:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2ceb9ec5ea22'	System	25 Aug 2020 00:29:59
User entered 'None (1)'	System	25 Aug 2020 00:29:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:29:57', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '8225e5f1-0299-40d8-859b-2eeb9ec5ea22'	System	25 Aug 2020 00:29:59
User entered '24 Aug 2020 19:29'	System	25 Aug 2020 00:29:59

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 6'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:30', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbfb-5593-42ff-914b-b2e3430a6ac5' User entered 'None (1)'	System	25 Aug 2020 22:27:04
	System	25 Aug 2020 22:27:04

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:36', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbfb-5593-42ff-914b-b2e3430a6ac5'	System	25 Aug 2020 22:27:04
User entered 'No (N)'	System	25 Aug 2020 22:27:04

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbfb-5593-42ff-914b-b2e3430a6ac5' User entered 'No (N)'	System	25 Aug 2020 22:27:04
	System	25 Aug 2020 22:27:04

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:49', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbfb-5593-42ff-914b-b2e3430a6ac5'	System	25 Aug 2020 22:27:04
User entered 'None (1)'	System	25 Aug 2020 22:27:04

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:26:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '785dbbfb-5593-42ff-914b-b2e3430a6ac5' User entered '25 Aug 2020 17:26'	System	25 Aug 2020 22:27:04
	System	25 Aug 2020 22:27:04

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 7'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:19:57', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' User entered 'None (1)'	System	26 Aug 2020 23:20:35
	System	26 Aug 2020 23:20:35

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:01', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' User entered 'No (N)'	System	26 Aug 2020 23:20:35
	System	26 Aug 2020 23:20:35

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:07', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' User entered 'No (N)'	System	26 Aug 2020 23:20:35
	System	26 Aug 2020 23:20:35

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' User entered 'None (1)'	System	26 Aug 2020 23:20:35
	System	26 Aug 2020 23:20:35

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:29', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '47551128-9b2c-4723-851b-f4fa1c49f8ef' User entered '26 Aug 2020 18:20'	System	26 Aug 2020 23:20:35
	System	26 Aug 2020 23:20:35

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:36', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' User entered 'None (0)'	System	20 Aug 2020 16:02:15
	System	20 Aug 2020 16:02:15

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' User entered 'None (0)'	System	20 Aug 2020 16:02:15
	System	20 Aug 2020 16:02:15

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' User entered 'None (0)'	System	20 Aug 2020 16:02:15
	System	20 Aug 2020 16:02:15

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' User entered 'None (0)'	System	20 Aug 2020 16:02:15
	System	20 Aug 2020 16:02:15

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:54', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' User entered 'None (0)'	System	20 Aug 2020 16:02:15
	System	20 Aug 2020 16:02:15

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:00:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' User entered 'None (0)'	System	20 Aug 2020 16:02:15
	System	20 Aug 2020 16:02:15

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:01:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' User entered 'No (N)'	System	20 Aug 2020 16:02:15
	System	20 Aug 2020 16:02:15

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T11:01:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '11174893-96c0-4f76-9cad-0228cf57e9cd' User entered '20 Aug 2020 11:01'	System	20 Aug 2020 16:02:15
	System	20 Aug 2020 16:02:15

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 10:34'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 13:04'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 1, after vaccination (at home)'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:36', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' User entered 'None (0)'	System	20 Aug 2020 23:30:24
	System	20 Aug 2020 23:30:24

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' User entered 'None (0)'	System	20 Aug 2020 23:30:24
	System	20 Aug 2020 23:30:24

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' User entered 'None (0)'	System	20 Aug 2020 23:30:24
	System	20 Aug 2020 23:30:24

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' User entered 'None (0)'	System	20 Aug 2020 23:30:24
	System	20 Aug 2020 23:30:24

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:52', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' User entered 'None (0)'	System	20 Aug 2020 23:30:24
	System	20 Aug 2020 23:30:24

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:29:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' User entered 'None (0)'	System	20 Aug 2020 23:30:24
	System	20 Aug 2020 23:30:24

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:30:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' User entered 'No (N)'	System	20 Aug 2020 23:30:24
	System	20 Aug 2020 23:30:24

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-20T18:30:19', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd49cb973-b9ad-4b1b-8672-6b591f80c19e' User entered '20 Aug 2020 18:30'	System	20 Aug 2020 23:30:24
	System	20 Aug 2020 23:30:24

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Aug 2020 13:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 2'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:04:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered 'None (0)'	System	21 Aug 2020 20:05:35
	System	21 Aug 2020 20:05:35

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered 'None (0)'	System	21 Aug 2020 20:05:35
	System	21 Aug 2020 20:05:35

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered 'None (0)'	System	21 Aug 2020 20:05:35
	System	21 Aug 2020 20:05:35

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered 'None (0)'	System	21 Aug 2020 20:05:35
	System	21 Aug 2020 20:05:35

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered 'None (0)'	System	21 Aug 2020 20:05:35
	System	21 Aug 2020 20:05:35

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered 'None (0)'	System	21 Aug 2020 20:05:35
	System	21 Aug 2020 20:05:35

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered 'No (N)'	System	21 Aug 2020 20:05:35
	System	21 Aug 2020 20:05:35

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-21T15:05:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c07687b-faaa-4d82-844a-9c45e51ed65c' User entered '21 Aug 2020 15:05'	System	21 Aug 2020 20:05:35
	System	21 Aug 2020 20:05:35

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 3'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:03:57', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)'	System	22 Aug 2020 23:04:44
	System	22 Aug 2020 23:04:44

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)'	System	22 Aug 2020 23:04:44
	System	22 Aug 2020 23:04:44

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)'	System	22 Aug 2020 23:04:44
	System	22 Aug 2020 23:04:44

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:11', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)'	System	22 Aug 2020 23:04:44
	System	22 Aug 2020 23:04:44

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)'	System	22 Aug 2020 23:04:44
	System	22 Aug 2020 23:04:44

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'None (0)'	System	22 Aug 2020 23:04:44
	System	22 Aug 2020 23:04:44

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered 'No (N)'	System	22 Aug 2020 23:04:44
	System	22 Aug 2020 23:04:44

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-22T18:04:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5075bcb-24da-4d4f-a395-1239d14750fb' User entered '22 Aug 2020 18:04'	System	22 Aug 2020 23:04:44
	System	22 Aug 2020 23:04:44

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 4'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:13', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' User entered 'None (0)'	System	23 Aug 2020 23:06:51
	System	23 Aug 2020 23:06:51

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' User entered 'None (0)'	System	23 Aug 2020 23:06:51
	System	23 Aug 2020 23:06:51

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' User entered 'None (0)'	System	23 Aug 2020 23:06:51
	System	23 Aug 2020 23:06:51

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' User entered 'None (0)'	System	23 Aug 2020 23:06:51
	System	23 Aug 2020 23:06:51

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' User entered 'None (0)'	System	23 Aug 2020 23:06:51
	System	23 Aug 2020 23:06:51

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' User entered 'None (0)'	System	23 Aug 2020 23:06:51
	System	23 Aug 2020 23:06:51

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:35', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4' User entered 'No (N)'	System	23 Aug 2020 23:06:51
	System	23 Aug 2020 23:06:51

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-23T18:06:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '08d55264-0556-4fdb-b9ac-bce2bf2d4ad4'	System	23 Aug 2020 23:06:51
User entered '23 Aug 2020 18:06'	System	23 Aug 2020 23:06:51

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 5'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' User entered 'None (0)'	System	25 Aug 2020 00:30:45
	System	25 Aug 2020 00:30:45

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' User entered 'None (0)'	System	25 Aug 2020 00:30:45
	System	25 Aug 2020 00:30:45

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' User entered 'None (0)'	System	25 Aug 2020 00:30:45
	System	25 Aug 2020 00:30:45

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:13', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' User entered 'None (0)'	System	25 Aug 2020 00:30:45
	System	25 Aug 2020 00:30:45

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' User entered 'None (0)'	System	25 Aug 2020 00:30:45
	System	25 Aug 2020 00:30:45

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:19', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' User entered 'None (0)'	System	25 Aug 2020 00:30:45
	System	25 Aug 2020 00:30:45

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' User entered 'No (N)'	System	25 Aug 2020 00:30:45
	System	25 Aug 2020 00:30:45

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-24T19:30:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae3287b9-3d43-42b6-80f5-9a5c52da3470' User entered '24 Aug 2020 19:30'	System	25 Aug 2020 00:30:45
	System	25 Aug 2020 00:30:45

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '25 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 6'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' User entered 'None (0)'	System	25 Aug 2020 22:27:42
	System	25 Aug 2020 22:27:42

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:07', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' User entered 'None (0)'	System	25 Aug 2020 22:27:42
	System	25 Aug 2020 22:27:42

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:11', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' User entered 'None (0)'	System	25 Aug 2020 22:27:42
	System	25 Aug 2020 22:27:42

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' User entered 'None (0)'	System	25 Aug 2020 22:27:42
	System	25 Aug 2020 22:27:42

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:19', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' User entered 'None (0)'	System	25 Aug 2020 22:27:42
	System	25 Aug 2020 22:27:42

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:21', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' User entered 'None (0)'	System	25 Aug 2020 22:27:42
	System	25 Aug 2020 22:27:42

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' User entered 'No (N)'	System	25 Aug 2020 22:27:42
	System	25 Aug 2020 22:27:42

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-25T17:27:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '26e49f1f-0359-4a31-a129-d0b4f05deb84' User entered '25 Aug 2020 17:27'	System	25 Aug 2020 22:27:42
	System	25 Aug 2020 22:27:42

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '25 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '26 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 7'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' User entered 'None (0)'	System	26 Aug 2020 23:21:13
	System	26 Aug 2020 23:21:13

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' User entered 'None (0)'	System	26 Aug 2020 23:21:13
	System	26 Aug 2020 23:21:13

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' User entered 'None (0)'	System	26 Aug 2020 23:21:13
	System	26 Aug 2020 23:21:13

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' User entered 'None (0)'	System	26 Aug 2020 23:21:13
	System	26 Aug 2020 23:21:13

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' User entered 'None (0)'	System	26 Aug 2020 23:21:13
	System	26 Aug 2020 23:21:13

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:54', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' User entered 'None (0)'	System	26 Aug 2020 23:21:13
	System	26 Aug 2020 23:21:13

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:20:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' User entered 'No (N)'	System	26 Aug 2020 23:21:13
	System	26 Aug 2020 23:21:13

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-08-26T18:21:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9bc9b411-2a55-4755-acff-8f14d68cd1bc' User entered '26 Aug 2020 18:21'	System	26 Aug 2020 23:21:13
	System	26 Aug 2020 23:21:13

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '26 Aug 2020 12:00'	System	20 Aug 2020 15:25:41

US3292236

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '27 Aug 2020 11:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:12:00
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	27 Aug 2020 18:12:28

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:12:00
User entered '27 Aug 2020'	Kristy Trevino (b) (4)	27 Aug 2020 18:12:28

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:12:00
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	27 Aug 2020 18:12:28

US3292236

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:12:00
User entered empty.	Kristy Trevino (b) (4)	27 Aug 2020 18:12:28

US3292236

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:14:24
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	27 Aug 2020 18:12:36

US3292236

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'l'	System	27 Aug 2020 18:12:36

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:50
User closed query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Sep 2020 15:07:43
User opened query 'Was Contact Attempted? = Yes and 'Date of Contact or Contact Attempt' or ' Please select one status for the follow-up contact' is missing. Please review and reconcile.' (Site from System).	System	03 Sep 2020 15:07:27
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	03 Sep 2020 15:07:27

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
DataPoint Verified.		15 Mar 2021 19:35:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Un-verified.	(b) (4) Antonio Gutierrez (b) (4)	10 Nov 2020 14:31:39
User entered '03 Sep 2020' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	10 Nov 2020 14:31:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:50
User entered '3 Sep 2020' reason for change: Data Entry Error	Kristy Trevino (b) (4)	03 Sep 2020 15:07:43
User entered empty.	(b) (4) Kristy Trevino (b) (4)	03 Sep 2020 15:07:27
	(b) (4)	

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:50
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	03 Sep 2020 15:07:27

US3292236

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:39:50
User entered empty.	Kristy Trevino (b) (4)	03 Sep 2020 15:07:27

US3292236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:40:04
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	03 Sep 2020 15:06:27

US3292236

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:48
User entered 'l'	System	03 Sep 2020 15:06:27

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:13:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:43:18
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	21 Sep 2020 22:28:16

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:13:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:43:18
User entered '10 Sep 2020'	Kevin Martinez (b) (4)	21 Sep 2020 22:28:16

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:13:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:43:18
User entered 'Contact Not Made (CONTACT NOT MADE)'	Kevin Martinez (b) (4)	21 Sep 2020 22:28:16

US3292236

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:13:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:43:18
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	21 Sep 2020 22:29:14
User entered 'Patient did not answer call.' reason for change: Data Entry Error	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:29:14
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	21 Sep 2020 22:28:16
User entered empty.	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:28:16

US3292236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:13:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	06 Nov 2020 16:43:28
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 16:08:54

US3292236

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:13:27
User entered 'l'	System	17 Sep 2020 16:08:54

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:44:08
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:11

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4) (h) (4)	22 Feb 2021 21:15:44
User closed query 'Per GCL Lab Recon: Sample for Visit 3 Day 57 dated Oct2020 is reported in PPD Central lab; however Visit is blank. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 09:52:50
DataPoint Verified.		06 Nov 2020 16:44:08
Query 'Per GCL Lab Recon: Sample for Visit 3 Day 57 dated Oct2020 is reported in PPD Central lab; however Visit is blank. Please reconcile. ' answered with 'UPDATED' (Site from DM).	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:46:22
User opened query 'Per GCL Lab Recon: Sample for Visit 3 Day 57 dated Oct2020 is reported in PPD Central lab; however Visit is blank. Please reconcile. ' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 01:31:19
User entered '17 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	17 Sep 2020 17:03:11

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[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 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:44:08
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:11

US3292236

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'VISIT2'	System	17 Sep 2020 17:03:11

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '17 Sep 2020'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '09:32'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered '17 Sep 2020 09:32'	System	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '36.3' C	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered 'Oral (Oral)'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered empty.	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '70'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'bpm'	System	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '17'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'breaths/min'	System	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '116'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'mmHg'	System	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '65'	Gerardo Pena (b) (4)	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'mmHg'	System	17 Sep 2020 17:03:47

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '17 Sep 2020'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '11:21'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered '17 Sep 2020 11:21'	System	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '36.8' C	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered 'Oral (Oral)'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered empty.	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '64'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'bpm'	System	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '20'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'breaths/min'	System	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '121'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'mmHg'	System	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:10
User entered '65'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'mmHg'	System	17 Sep 2020 17:04:37

US3292236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:30
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:48

US3292236

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:30
User entered '17 Sep 2020'	Gerardo Pena (b) (4)	17 Sep 2020 17:04:48

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	06 Nov 2020 16:45:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	06 Nov 2020 16:45:42
User entered empty.	(b) (4), (b) (6)	17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:45:42
User entered empty.		17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'MRNA-1273 OR PLACEBO'	System	17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:45:42
User entered '17 Sep 2020'		17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	06 Nov 2020 16:45:42
User entered '10:49'	(b) (4), (b) (6)	17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered '17 Sep 2020 10:49'	System	17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	06 Nov 2020 16:45:42
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
DataPoint Verified.		06 Nov 2020 16:45:42
User entered 'ONCE'	System	17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'INTRAMUSCULAR'	System	17 Sep 2020 16:09:13

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:55
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	17 Sep 2020 17:05:23

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:55
User entered '17 Sep 2020'	Gerardo Pena (b) (4)	17 Sep 2020 17:05:23

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:45:55
User entered '09:42'	Gerardo Pena (b) (4)	17 Sep 2020 17:05:23

US3292236

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered '17 Sep 2020 09:42'	System	17 Sep 2020 17:05:23

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:46:14
User entered '17 Sep 2020'	Gerardo Pena (b) (4)	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:46:14
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:46:14
User entered '10:00'	Gerardo Pena (b) (4)	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:28:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered '17 Sep 2020 10:00'	System	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:29

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:46:14
User entered 'No (N)'	Gerardo Pena (b) (4)	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:46:14
User entered empty.	Gerardo Pena (b) (4)	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:28:29

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered empty.	System	17 Sep 2020 17:05:39

US3292236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:46:22
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	17 Sep 2020 17:05:48

US3292236

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'I'	System	17 Sep 2020 17:05:48

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:25:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3a9acaeb-d473-4762-bce9-047364727148' User entered 'Yes (Y)'	System	17 Sep 2020 16:26:06
	System	17 Sep 2020 16:26:06

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:25:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3a9acaeb-d473-4762-bce9-047364727148' User entered '98.2'	System	17 Sep 2020 16:26:06
	System	17 Sep 2020 16:26:06

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:25:36', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3a9acaeb-d473-4762-bce9-047364727148' User entered 'No (N)'	System	17 Sep 2020 16:26:06
	System	17 Sep 2020 16:26:06

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3a9acaeb-d473-4762-bce9-047364727148' User entered '17 Sep 2020 11:26'	System	17 Sep 2020 16:26:06
	System	17 Sep 2020 16:26:06

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 11:09'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 13:39'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '395cd8c3-4d74-4990-8027-537fa21dd168' User entered 'Yes (Y)'	System	17 Sep 2020 20:44:41
	System	17 Sep 2020 20:44:41

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '395cd8c3-4d74-4990-8027-537fa21dd168' User entered '94.4'	System	17 Sep 2020 20:44:41
	System	17 Sep 2020 20:44:41

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '395cd8c3-4d74-4990-8027-537fa21dd168'	System	17 Sep 2020 20:44:41
User entered 'No (N)'	System	17 Sep 2020 20:44:41

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '395cd8c3-4d74-4990-8027-537fa21dd168' User entered '17 Sep 2020 15:44'	System	17 Sep 2020 20:44:41
	System	17 Sep 2020 20:44:41

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 14:34'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 2'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:20:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '31390f3f-af0c-4cdc-96de-7864643f7340' User entered 'Yes (Y)'	System	18 Sep 2020 21:20:55
	System	18 Sep 2020 21:20:55

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:20:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '31390f3f-af0c-4cdc-96de-7864643f7340' User entered '97.8'	System	18 Sep 2020 21:20:55
	System	18 Sep 2020 21:20:55

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:20:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '31390f3f-af0c-4cdc-96de-7864643f7340'	System	18 Sep 2020 21:20:55
User entered 'No (N)'	System	18 Sep 2020 21:20:55

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:20:51', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '31390f3f-af0c-4cdc-96de-7864643f7340'	System	18 Sep 2020 21:20:55
User entered '18 Sep 2020 16:20'	System	18 Sep 2020 21:20:55

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 3'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:02:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5a39625-e1d1-4873-b06e-5cbc336e24a5' User entered 'Yes (Y)'	System	20 Sep 2020 02:03:17
	System	20 Sep 2020 02:03:17

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:02:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5a39625-e1d1-4873-b06e-5cbc336e24a5' User entered '97.8'	System	20 Sep 2020 02:03:17
	System	20 Sep 2020 02:03:17

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5a39625-e1d1-4873-b06e-5cbc336e24a5'	System	20 Sep 2020 02:03:17
User entered 'No (N)'	System	20 Sep 2020 02:03:17

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:13', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f5a39625-e1d1-4873-b06e-5cbc336e24a5' User entered '19 Sep 2020 21:03'	System	20 Sep 2020 02:03:17
	System	20 Sep 2020 02:03:17

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 4'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '302686a2-73a4-440d-920a-d1728f377087' User entered 'Yes (Y)'	System	20 Sep 2020 23:54:49
	System	20 Sep 2020 23:54:49

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:32', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '302686a2-73a4-440d-920a-d1728f377087' User entered '97.8'	System	20 Sep 2020 23:54:49
	System	20 Sep 2020 23:54:49

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:39', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '302686a2-73a4-440d-920a-d1728f377087'	System	20 Sep 2020 23:54:49
User entered 'No (N)'	System	20 Sep 2020 23:54:49

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '302686a2-73a4-440d-920a-d1728f377087' User entered '20 Sep 2020 18:54'	System	20 Sep 2020 23:54:49
	System	20 Sep 2020 23:54:49

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 5'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '32e23df3-55a5-46a8-88d3-5217584159af' User entered 'Yes (Y)'	System	21 Sep 2020 22:20:36
	System	21 Sep 2020 22:20:36

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '32e23df3-55a5-46a8-88d3-5217584159af' User entered '97.8'	System	21 Sep 2020 22:20:36
	System	21 Sep 2020 22:20:36

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '32e23df3-55a5-46a8-88d3-5217584159af' User entered 'No (N)'	System	21 Sep 2020 22:20:36
	System	21 Sep 2020 22:20:36

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '32e23df3-55a5-46a8-88d3-5217584159af' User entered '21 Sep 2020 17:20'	System	21 Sep 2020 22:20:36
	System	21 Sep 2020 22:20:36

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 6'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:34:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5526a3aa-54e1-4070-86ad-baf284e18fda' User entered 'Yes (Y)'	System	22 Sep 2020 22:34:54
	System	22 Sep 2020 22:34:54

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:34:34', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5526a3aa-54e1-4070-86ad-baf284e18fda' User entered '97.6'	System	22 Sep 2020 22:34:54
	System	22 Sep 2020 22:34:54

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:34:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5526a3aa-54e1-4070-86ad-baf284e18fda'	System	22 Sep 2020 22:34:54
User entered 'No (N)'	System	22 Sep 2020 22:34:54

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:34:52', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5526a3aa-54e1-4070-86ad-baf284e18fda' User entered '22 Sep 2020 17:34'	System	22 Sep 2020 22:34:54
	System	22 Sep 2020 22:34:54

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 7'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9f562f9b-6ef8-418c-8f32-8cea3fe617bd' User entered 'Yes (Y)'	System	24 Sep 2020 11:17:30
	System	24 Sep 2020 11:17:30

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9f562f9b-6ef8-418c-8f32-8cea3fe617bd' User entered '97.4'	System	24 Sep 2020 11:17:30
	System	24 Sep 2020 11:17:30

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9f562f9b-6ef8-418c-8f32-8cea3fe617bd'	System	24 Sep 2020 11:17:30
User entered 'No (N)'	System	24 Sep 2020 11:17:30

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9f562f9b-6ef8-418c-8f32-8cea3fe617bd' User entered '24 Sep 2020 06:17'	System	24 Sep 2020 11:17:30
	System	24 Sep 2020 11:17:30

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fcccc' User entered 'None (1)'	System	17 Sep 2020 16:26:51
	System	17 Sep 2020 16:26:51

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fceed' User entered 'No (N)'	System	17 Sep 2020 16:26:51
	System	17 Sep 2020 16:26:51

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:29', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fcccc' User entered 'No (N)'	System	17 Sep 2020 16:26:51
	System	17 Sep 2020 16:26:51

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fcccc' User entered 'None (1)'	System	17 Sep 2020 16:26:51
	System	17 Sep 2020 16:26:51

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '43aa98bb-19dc-4cd1-9da7-7e17824fceed'	System	17 Sep 2020 16:26:51
User entered '17 Sep 2020 11:26'	System	17 Sep 2020 16:26:51

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 11:09'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 13:39'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' User entered 'None (1)'	System	17 Sep 2020 20:45:18
	System	17 Sep 2020 20:45:18

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' User entered 'No (N)'	System	17 Sep 2020 20:45:18
	System	17 Sep 2020 20:45:18

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:44:57', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' User entered 'No (N)'	System	17 Sep 2020 20:45:18
	System	17 Sep 2020 20:45:18

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' User entered 'None (1)'	System	17 Sep 2020 20:45:18
	System	17 Sep 2020 20:45:18

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '98846e73-d2c4-4f99-ad73-5e78c860138e' User entered '17 Sep 2020 15:45'	System	17 Sep 2020 20:45:18
	System	17 Sep 2020 20:45:18

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 14:34'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 2'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' User entered 'None (1)'	System	18 Sep 2020 21:21:39
	System	18 Sep 2020 21:21:39

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' User entered 'No (N)'	System	18 Sep 2020 21:21:39
	System	18 Sep 2020 21:21:39

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' User entered 'No (N)'	System	18 Sep 2020 21:21:39
	System	18 Sep 2020 21:21:39

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' User entered 'None (1)'	System	18 Sep 2020 21:21:39
	System	18 Sep 2020 21:21:39

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '25839774-93ed-45e1-abdd-2bd5ea7e4b1d' User entered '18 Sep 2020 16:21'	System	18 Sep 2020 21:21:39
	System	18 Sep 2020 21:21:39

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 3'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190'	System	20 Sep 2020 02:04:04
User entered 'None (1)'	System	20 Sep 2020 02:04:04

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190'	System	20 Sep 2020 02:04:04
User entered 'No (N)'	System	20 Sep 2020 02:04:04

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190' User entered 'No (N)'	System	20 Sep 2020 02:04:04
	System	20 Sep 2020 02:04:04

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190'	System	20 Sep 2020 02:04:04
User entered 'None (1)'	System	20 Sep 2020 02:04:04

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:03:55', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '419e7ce3-c0bf-41ab-a91e-83599dad7190' User entered '19 Sep 2020 21:03'	System	20 Sep 2020 02:04:04
	System	20 Sep 2020 02:04:04

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 4'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:55', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019'	System	20 Sep 2020 23:55:21
User entered 'None (1)'	System	20 Sep 2020 23:55:21

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:54:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019' User entered 'No (N)'	System	20 Sep 2020 23:55:21
	System	20 Sep 2020 23:55:21

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019' User entered 'No (N)'	System	20 Sep 2020 23:55:21
	System	20 Sep 2020 23:55:21

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:11', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019'	System	20 Sep 2020 23:55:21
User entered 'None (1)'	System	20 Sep 2020 23:55:21

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'bfaa9da3-c3c4-4805-a5ed-2d9d6bfd5019' User entered '20 Sep 2020 18:55'	System	20 Sep 2020 23:55:21
	System	20 Sep 2020 23:55:21

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 5'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' User entered 'None (1)'	System	21 Sep 2020 22:21:14
	System	21 Sep 2020 22:21:14

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' User entered 'No (N)'	System	21 Sep 2020 22:21:14
	System	21 Sep 2020 22:21:14

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:53', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' User entered 'No (N)'	System	21 Sep 2020 22:21:14
	System	21 Sep 2020 22:21:14

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:20:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' User entered 'None (1)'	System	21 Sep 2020 22:21:14
	System	21 Sep 2020 22:21:14

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '215aeba0-4efa-4de4-be2e-5316d426a68e' User entered '21 Sep 2020 17:21'	System	21 Sep 2020 22:21:14
	System	21 Sep 2020 22:21:14

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 6'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127'	System	22 Sep 2020 22:35:31
User entered 'None (1)'	System	22 Sep 2020 22:35:31

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127'	System	22 Sep 2020 22:35:31
User entered 'No (N)'	System	22 Sep 2020 22:35:31

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:11', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127' User entered 'No (N)'	System	22 Sep 2020 22:35:31
	System	22 Sep 2020 22:35:31

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127'	System	22 Sep 2020 22:35:31
User entered 'None (1)'	System	22 Sep 2020 22:35:31

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:27', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6c946c9b-2848-4499-bb65-dc8d8f391127' User entered '22 Sep 2020 17:35'	System	22 Sep 2020 22:35:31
	System	22 Sep 2020 22:35:31

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 7'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:32', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2'	System	24 Sep 2020 11:17:58
User entered 'None (1)'	System	24 Sep 2020 11:17:58

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:39', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2' User entered 'No (N)'	System	24 Sep 2020 11:17:58
	System	24 Sep 2020 11:17:58

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:42', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2' User entered 'No (N)'	System	24 Sep 2020 11:17:58
	System	24 Sep 2020 11:17:58

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:46', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2'	System	24 Sep 2020 11:17:58
User entered 'None (1)'	System	24 Sep 2020 11:17:58

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:17:55', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '245524de-91d6-4b2e-b813-fb83a9bcdef2' User entered '24 Sep 2020 06:17'	System	24 Sep 2020 11:17:58
	System	24 Sep 2020 11:17:58

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:26:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' User entered 'None (0)'	System	17 Sep 2020 16:27:40
	System	17 Sep 2020 16:27:40

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' User entered 'None (0)'	System	17 Sep 2020 16:27:40
	System	17 Sep 2020 16:27:40

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:10', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' User entered 'None (0)'	System	17 Sep 2020 16:27:40
	System	17 Sep 2020 16:27:40

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' User entered 'None (0)'	System	17 Sep 2020 16:27:40
	System	17 Sep 2020 16:27:40

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' User entered 'None (0)'	System	17 Sep 2020 16:27:40
	System	17 Sep 2020 16:27:40

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:26', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' User entered 'None (0)'	System	17 Sep 2020 16:27:40
	System	17 Sep 2020 16:27:40

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' User entered 'No (N)'	System	17 Sep 2020 16:27:40
	System	17 Sep 2020 16:27:40

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T11:27:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cc9e9e78-2f02-4fb2-bd7a-21dfb815bdc1' User entered '17 Sep 2020 11:27'	System	17 Sep 2020 16:27:40
	System	17 Sep 2020 16:27:40

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 11:09'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 13:39'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 1, after vaccination (at home)'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' User entered 'None (0)'	System	17 Sep 2020 20:46:10
	System	17 Sep 2020 20:46:10

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' User entered 'None (0)'	System	17 Sep 2020 20:46:10
	System	17 Sep 2020 20:46:10

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:30', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' User entered 'None (0)'	System	17 Sep 2020 20:46:10
	System	17 Sep 2020 20:46:10

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:35', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' User entered 'None (0)'	System	17 Sep 2020 20:46:10
	System	17 Sep 2020 20:46:10

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' User entered 'None (0)'	System	17 Sep 2020 20:46:10
	System	17 Sep 2020 20:46:10

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' User entered 'None (0)'	System	17 Sep 2020 20:46:10
	System	17 Sep 2020 20:46:10

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:45:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343'	System	17 Sep 2020 20:46:10
User entered 'No (N)'	System	17 Sep 2020 20:46:10

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-17T15:46:07', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0651cac7-3977-49fb-ab83-c2e89ffe5343' User entered '17 Sep 2020 15:46'	System	17 Sep 2020 20:46:10
	System	17 Sep 2020 20:46:10

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '17 Sep 2020 14:34'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '18 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 2'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:44', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' User entered 'None (0)'	System	18 Sep 2020 21:22:27
	System	18 Sep 2020 21:22:27

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:48', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' User entered 'None (0)'	System	18 Sep 2020 21:22:27
	System	18 Sep 2020 21:22:27

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:52', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' User entered 'None (0)'	System	18 Sep 2020 21:22:27
	System	18 Sep 2020 21:22:27

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' User entered 'None (0)'	System	18 Sep 2020 21:22:27
	System	18 Sep 2020 21:22:27

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:21:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' User entered 'None (0)'	System	18 Sep 2020 21:22:27
	System	18 Sep 2020 21:22:27

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:22:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' User entered 'None (0)'	System	18 Sep 2020 21:22:27
	System	18 Sep 2020 21:22:27

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:22:08', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' User entered 'No (N)'	System	18 Sep 2020 21:22:27
	System	18 Sep 2020 21:22:27

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-18T16:22:23', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'd9fe13c0-315e-46be-abc0-d2b8811a25c3' User entered '18 Sep 2020 16:22'	System	18 Sep 2020 21:22:27
	System	18 Sep 2020 21:22:27

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '18 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '19 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 3'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:01', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' User entered 'None (0)'	System	20 Sep 2020 02:04:42
	System	20 Sep 2020 02:04:42

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:05', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' User entered 'None (0)'	System	20 Sep 2020 02:04:42
	System	20 Sep 2020 02:04:42

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' User entered 'None (0)'	System	20 Sep 2020 02:04:42
	System	20 Sep 2020 02:04:42

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' User entered 'None (0)'	System	20 Sep 2020 02:04:42
	System	20 Sep 2020 02:04:42

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' User entered 'None (0)'	System	20 Sep 2020 02:04:42
	System	20 Sep 2020 02:04:42

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:19', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' User entered 'None (0)'	System	20 Sep 2020 02:04:42
	System	20 Sep 2020 02:04:42

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' User entered 'No (N)'	System	20 Sep 2020 02:04:42
	System	20 Sep 2020 02:04:42

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-19T21:04:39', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'b25028b2-fa31-455a-b798-c0e73dcbb273' User entered '19 Sep 2020 21:04'	System	20 Sep 2020 02:04:42
	System	20 Sep 2020 02:04:42

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '19 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 4'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:25', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' User entered 'None (0)'	System	20 Sep 2020 23:56:03
	System	20 Sep 2020 23:56:03

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' User entered 'None (0)'	System	20 Sep 2020 23:56:03
	System	20 Sep 2020 23:56:03

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' User entered 'None (0)'	System	20 Sep 2020 23:56:03
	System	20 Sep 2020 23:56:03

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' User entered 'None (0)'	System	20 Sep 2020 23:56:03
	System	20 Sep 2020 23:56:03

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' User entered 'None (0)'	System	20 Sep 2020 23:56:03
	System	20 Sep 2020 23:56:03

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' User entered 'None (0)'	System	20 Sep 2020 23:56:03
	System	20 Sep 2020 23:56:03

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:55:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' User entered 'No (N)'	System	20 Sep 2020 23:56:03
	System	20 Sep 2020 23:56:03

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-20T18:56:01', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e72c2781-3854-4d4b-8112-ad37f417aa5c' User entered '20 Sep 2020 18:56'	System	20 Sep 2020 23:56:03
	System	20 Sep 2020 23:56:03

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '20 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 5'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' User entered 'None (0)'	System	21 Sep 2020 22:21:59
	System	21 Sep 2020 22:21:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:22', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' User entered 'None (0)'	System	21 Sep 2020 22:21:59
	System	21 Sep 2020 22:21:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:26', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' User entered 'None (0)'	System	21 Sep 2020 22:21:59
	System	21 Sep 2020 22:21:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' User entered 'None (0)'	System	21 Sep 2020 22:21:59
	System	21 Sep 2020 22:21:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:34', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' User entered 'None (0)'	System	21 Sep 2020 22:21:59
	System	21 Sep 2020 22:21:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' User entered 'None (0)'	System	21 Sep 2020 22:21:59
	System	21 Sep 2020 22:21:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:42', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59'	System	21 Sep 2020 22:21:59
User entered 'No (N)'	System	21 Sep 2020 22:21:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-21T17:21:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c5adc57b-6045-4cba-af17-6c6ee44b4f59' User entered '21 Sep 2020 17:21'	System	21 Sep 2020 22:21:59
	System	21 Sep 2020 22:21:59

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '21 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 6'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' User entered 'None (0)'	System	22 Sep 2020 22:36:21
	System	22 Sep 2020 22:36:21

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' User entered 'None (0)'	System	22 Sep 2020 22:36:21
	System	22 Sep 2020 22:36:21

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' User entered 'None (0)'	System	22 Sep 2020 22:36:21
	System	22 Sep 2020 22:36:21

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:35:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' User entered 'None (0)'	System	22 Sep 2020 22:36:21
	System	22 Sep 2020 22:36:21

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:36:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' User entered 'None (0)'	System	22 Sep 2020 22:36:21
	System	22 Sep 2020 22:36:21

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:36:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' User entered 'None (0)'	System	22 Sep 2020 22:36:21
	System	22 Sep 2020 22:36:21

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:36:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' User entered 'No (N)'	System	22 Sep 2020 22:36:21
	System	22 Sep 2020 22:36:21

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-22T17:36:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7ef4493-2ea2-422b-b23f-d284b74b8aa1' User entered '22 Sep 2020 17:36'	System	22 Sep 2020 22:36:21
	System	22 Sep 2020 22:36:21

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '22 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	17 Sep 2020 16:09:13
User entered 'Day 7'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' User entered 'None (0)'	System	24 Sep 2020 11:18:30
	System	24 Sep 2020 11:18:30

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' User entered 'None (0)'	System	24 Sep 2020 11:18:30
	System	24 Sep 2020 11:18:30

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:06', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' User entered 'None (0)'	System	24 Sep 2020 11:18:30
	System	24 Sep 2020 11:18:30

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' User entered 'None (0)'	System	24 Sep 2020 11:18:30
	System	24 Sep 2020 11:18:30

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' User entered 'None (0)'	System	24 Sep 2020 11:18:30
	System	24 Sep 2020 11:18:30

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' User entered 'None (0)'	System	24 Sep 2020 11:18:30
	System	24 Sep 2020 11:18:30

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:18', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' User entered 'No (N)'	System	24 Sep 2020 11:18:30
	System	24 Sep 2020 11:18:30

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-09-24T06:18:29', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '9c03fe36-6f3c-4c9c-8d39-9edefc395e00' User entered '24 Sep 2020 06:18'	System	24 Sep 2020 11:18:30
	System	24 Sep 2020 11:18:30

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '23 Sep 2020 12:00'	System	17 Sep 2020 16:09:13

US3292236

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:28:29

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
User entered '24 Sep 2020 11:59'	System	17 Sep 2020 16:09:13

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:47:54
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	28 Sep 2020 15:41:55

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:47:54
User entered '25 Sep 2020'	Kristy Trevino (b) (4)	28 Sep 2020 15:41:55

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:47:54
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	28 Sep 2020 15:41:55

US3292236

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:47:54
User entered empty.	Kristy Trevino (b) (4)	28 Sep 2020 15:41:55

US3292236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:48:01
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	28 Sep 2020 15:47:58

US3292236

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'I'	System	28 Sep 2020 15:47:58

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:48:36
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	02 Oct 2020 16:55:52

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:48:36
User entered '2 Oct 2020'	Kristy Trevino (b) (4)	02 Oct 2020 16:55:52

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:48:36
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	02 Oct 2020 16:55:52

US3292236

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:48:36
User entered empty.	Kristy Trevino (b) (4)	02 Oct 2020 16:55:52

US3292236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:48:42
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	02 Oct 2020 16:58:32

US3292236

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'l'	System	02 Oct 2020 16:58:32

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	06 Nov 2020 16:52:20
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:12:26

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:52:20
User entered '9 Oct 2020'		09 Oct 2020 14:12:26

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	06 Nov 2020 16:52:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	09 Oct 2020 14:12:26

US3292236

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	06 Nov 2020 16:52:20
User entered empty.	(b) (4), (b) (6)	09 Oct 2020 14:12:26

US3292236

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	06 Nov 2020 16:52:26
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Oct 2020 14:12:31

US3292236

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'l'	System	09 Oct 2020 14:12:31

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:25
User entered 'Yes (Y)'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:44:41

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 18:53:25
User entered '15 Oct 2020'	Victoria Hernandez (b) (4)	05 Nov 2020 19:44:41

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[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 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:25
User entered 'Clinic (Clinic)'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:44:41

US3292236

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'VISIT3'	System	05 Nov 2020 19:44:41

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered 'Yes (Y)'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered '15 Oct 2020'	Victoria Hernandez (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered '11:00'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered '15 Oct 2020 11:00'	System	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered '36.7' C	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered 'Oral (Oral)'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered empty.	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered '74'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'bpm'	System	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered '16'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'breaths/min'	System	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:25
User entered '103'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'mmHg'	System	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4)	14 Jan 2021 18:52:25
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	10 Nov 2020 20:45:55
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Victoria Hernandez (b) (4)	05 Nov 2020 19:45:31
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		05 Nov 2020 19:45:21
User entered '59'	Victoria Hernandez (b) (4)	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'mmHg'	System	05 Nov 2020 19:45:21

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15

US3292236

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15

US3292236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:52:49
User entered 'No (N)'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:45:43

US3292236

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4), (b) (6)	14 Jan 2021 18:52:49
User entered empty.	Victoria Hernandez (b) (4)	05 Nov 2020 19:45:43

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:00
User entered 'Yes (Y)'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:46:05

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:00
User entered '15 Oct 2020'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:46:05

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:00
User entered '11:10'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:46:05

US3292236

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered '15 Oct 2020 11:10'	System	05 Nov 2020 19:46:05

US3292236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Jan 2021 18:53:08
User entered 'Yes (Y)'	Victoria Hernandez (b) (4) (b) (4)	05 Nov 2020 19:46:11

US3292236

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'I'	System	05 Nov 2020 19:46:11

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 64'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-20T05:33:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3dd4520e-daf7-4991-82b6-ee962d1f9c22'	System	20 Oct 2020 10:33:31
User entered 'No (N)'	System	20 Oct 2020 10:33:31

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-20T05:33:09', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3dd4520e-daf7-4991-82b6-ee962d1f9c22'	System	20 Oct 2020 10:33:31
User entered 'No (N)'	System	20 Oct 2020 10:33:31

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-20T05:33:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3dd4520e-daf7-4991-82b6-ee962d1f9c22' User entered '20 Oct 2020 05:33:28'	System	20 Oct 2020 10:33:31
	System	20 Oct 2020 10:33:31

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered '20 Oct 2020 00:01'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered '24 Oct 2020 23:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 71'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-28T09:18:41', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '07cf0f05-4287-4513-9da8-073aa1674126'	System	28 Oct 2020 14:19:01
User entered 'No (N)'	System	28 Oct 2020 14:19:01

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-28T09:18:45', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '07cf0f05-4287-4513-9da8-073aa1674126'	System	28 Oct 2020 14:19:01
User entered 'No (N)'	System	28 Oct 2020 14:19:01

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-10-28T09:18:59', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '07cf0f05-4287-4513-9da8-073aa1674126' User entered '28 Oct 2020 09:18:59'	System	28 Oct 2020 14:19:01
	System	28 Oct 2020 14:19:01

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered '27 Oct 2020 00:01'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered '31 Oct 2020 23:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 78'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-04T10:40:46', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5a10a23c-8e68-473b-a6ab-d110d643fe43'	System	04 Nov 2020 16:41:01
User entered 'No (N)'	System	04 Nov 2020 16:41:01

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-04T10:40:52', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5a10a23c-8e68-473b-a6ab-d110d643fe43'	System	04 Nov 2020 16:41:01
User entered 'No (N)'	System	04 Nov 2020 16:41:01

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-04T10:40:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '5a10a23c-8e68-473b-a6ab-d110d643fe43' User entered '04 Nov 2020 10:40:58'	System	04 Nov 2020 16:41:01
	System	04 Nov 2020 16:41:01

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered '03 Nov 2020 00:01'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered '07 Nov 2020 23:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered 'Day 92'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-17T12:58:21', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2f1cfc39-35f7-4169-ba9f-e6780b344d33'	System	17 Nov 2020 18:58:36
User entered 'No (N)'	System	17 Nov 2020 18:58:36

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-17T12:58:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2f1cfc39-35f7-4169-ba9f-e6780b344d33'	System	17 Nov 2020 18:58:36
User entered 'No (N)'	System	17 Nov 2020 18:58:36

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-17T12:58:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2f1cfc39-35f7-4169-ba9f-e6780b344d33'	System	17 Nov 2020 18:58:36
User entered '17 Nov 2020 12:58:31'	System	17 Nov 2020 18:58:36

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered '17 Nov 2020 00:01'	System	20 Aug 2020 15:25:41

US3292236

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:05:47
Data entry locked.	System	20 Aug 2020 15:25:41
User entered '21 Nov 2020 23:59'	System	20 Aug 2020 15:25:41

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-22T09:47:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'da408f1c-365c-44f7-9170-36022859265c' User entered 'No (N)'	System	22 Nov 2020 15:47:29

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-22T09:47:17', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'da408f1c-365c-44f7-9170-36022859265c' User entered 'No (N)'	System	22 Nov 2020 15:47:29

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-22T09:47:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'da408f1c-365c-44f7-9170-36022859265c' User entered '22 Nov 2020 09:47:24'	System	22 Nov 2020 15:47:29
	System	22 Nov 2020 15:47:29

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '21 Nov 2020 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '25 Nov 2020 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-30T12:00:40', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '247ba69c-5e70-4f0a-835d-6a35a5be0f86' User entered 'No (N)'	System	30 Nov 2020 18:00:57

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-30T12:00:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '247ba69c-5e70-4f0a-835d-6a35a5be0f86' User entered 'No (N)'	System	30 Nov 2020 18:00:57

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-11-30T12:00:50', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '247ba69c-5e70-4f0a-835d-6a35a5be0f86' User entered '30 Nov 2020 12:00:50'	System	30 Nov 2020 18:00:57
	System	30 Nov 2020 18:00:57

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '28 Nov 2020 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '02 Dec 2020 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-05T13:36:54', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6e818038-e418-46c6-9768-05d37014e05f' User entered 'No (N)'	System	05 Dec 2020 19:37:17
	System	05 Dec 2020 19:37:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-05T13:37:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6e818038-e418-46c6-9768-05d37014e05f' User entered 'No (N)'	System	05 Dec 2020 19:37:17
	System	05 Dec 2020 19:37:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-05T13:37:13', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '6e818038-e418-46c6-9768-05d37014e05f' User entered '05 Dec 2020 13:37:13'	System	05 Dec 2020 19:37:17
	System	05 Dec 2020 19:37:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '05 Dec 2020 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '09 Dec 2020 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-12T06:06:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7aba0949-4cca-4d40-8c0c-af150528d29c' User entered 'No (N)'	System	12 Dec 2020 12:06:23
	System	12 Dec 2020 12:06:23

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-12T06:06:10', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7aba0949-4cca-4d40-8c0c-af150528d29c'	System	12 Dec 2020 12:06:23
User entered 'No (N)'	System	12 Dec 2020 12:06:23

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-12T06:06:17', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7aba0949-4cca-4d40-8c0c-af150528d29c' User entered '12 Dec 2020 06:06:17'	System	12 Dec 2020 12:06:23
	System	12 Dec 2020 12:06:23

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '12 Dec 2020 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '16 Dec 2020 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-21T12:13:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3c980c50-503b-4030-a720-42ba70cb998e' User entered 'No (N)'	System	21 Dec 2020 18:13:36
	System	21 Dec 2020 18:13:36

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-21T12:13:28', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3c980c50-503b-4030-a720-42ba70cb998e' User entered 'No (N)'	System	21 Dec 2020 18:13:36
	System	21 Dec 2020 18:13:36

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-21T12:13:33', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3c980c50-503b-4030-a720-42ba70cb998e' User entered '21 Dec 2020 12:13:33'	System	21 Dec 2020 18:13:36
	System	21 Dec 2020 18:13:36

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '19 Dec 2020 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '23 Dec 2020 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-28T12:01:32', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3708e1ee-109b-4d99-8693-f7037bcdcd0'	System	28 Dec 2020 18:01:47
User entered 'No (N)'	System	28 Dec 2020 18:01:47

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-28T12:01:37', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3708e1ee-109b-4d99-8693-f7037bcdcd0'	System	28 Dec 2020 18:01:47
User entered 'No (N)'	System	28 Dec 2020 18:01:47

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2020-12-28T12:01:43', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3708e1ee-109b-4d99-8693-f7037bcdcd0' User entered '28 Dec 2020 12:01:43'	System	28 Dec 2020 18:01:47
	System	28 Dec 2020 18:01:47

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '26 Dec 2020 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '30 Dec 2020 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-04T11:03:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3d318eb3-efb1-4b18-bcc4-a54c0752ef0b' User entered 'No (N)'	System	04 Jan 2021 17:03:37
	System	04 Jan 2021 17:03:37

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-04T11:03:21', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3d318eb3-efb1-4b18-bcc4-a54c0752ef0b' User entered 'No (N)'	System	04 Jan 2021 17:03:37

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-04T11:03:31', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '3d318eb3-efb1-4b18-bcc4-a54c0752ef0b' User entered '04 Jan 2021 11:03:31'	System	04 Jan 2021 17:03:37
	System	04 Jan 2021 17:03:37

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '02 Jan 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '06 Jan 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-11T10:16:35', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f3c1cac8-be93-4aa9-a821-d9f218fc0988' User entered 'No (N)'	System	11 Jan 2021 16:16:45

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-11T10:16:38', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f3c1cac8-be93-4aa9-a821-d9f218fc0988' User entered 'No (N)'	System	11 Jan 2021 16:16:45
	System	11 Jan 2021 16:16:45

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-11T10:16:42', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'f3c1cac8-be93-4aa9-a821-d9f218fc0988' User entered '11 Jan 2021 10:16:42'	System	11 Jan 2021 16:16:45
	System	11 Jan 2021 16:16:45

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '09 Jan 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '13 Jan 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-16T12:48:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2a3a97c8-9ab9-4c4b-990b-fd8ad8e41137' User entered 'No (N)'	System	16 Jan 2021 18:49:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-16T12:49:02', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2a3a97c8-9ab9-4c4b-990b-fd8ad8e41137'	System	16 Jan 2021 18:49:17
User entered 'No (N)'	System	16 Jan 2021 18:49:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-16T12:49:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '2a3a97c8-9ab9-4c4b-990b-fd8ad8e41137' User entered '16 Jan 2021 12:49:14'	System	16 Jan 2021 18:49:17
	System	16 Jan 2021 18:49:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '16 Jan 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '20 Jan 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-23T06:32:14', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a345b4c-df80-4207-8c84-7f5c68b34a32'	System	23 Jan 2021 12:32:27
User entered 'No (N)'	System	23 Jan 2021 12:32:27

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-23T06:32:20', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a345b4c-df80-4207-8c84-7f5c68b34a32'	System	23 Jan 2021 12:32:27
User entered 'No (N)'	System	23 Jan 2021 12:32:27

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-23T06:32:24', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0a345b4c-df80-4207-8c84-7f5c68b34a32' User entered '23 Jan 2021 06:32:24'	System	23 Jan 2021 12:32:27
	System	23 Jan 2021 12:32:27

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '23 Jan 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '27 Jan 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-31T14:21:47', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7690151-7af3-4a87-bc17-7509ec44f3e4' User entered 'No (N)'	System	31 Jan 2021 20:21:58
	System	31 Jan 2021 20:21:58

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-31T14:21:53', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7690151-7af3-4a87-bc17-7509ec44f3e4'	System	31 Jan 2021 20:21:58
User entered 'No (N)'	System	31 Jan 2021 20:21:58

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-01-31T14:21:56', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'e7690151-7af3-4a87-bc17-7509ec44f3e4' User entered '31 Jan 2021 14:21:56'	System	31 Jan 2021 20:21:58
	System	31 Jan 2021 20:21:58

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '30 Jan 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '03 Feb 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-08T08:31:55', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '12beac42-4c74-4c3c-8290-8897ccc82e7d' User entered 'No (N)'	System	08 Feb 2021 14:32:17
	System	08 Feb 2021 14:32:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-08T08:32:10', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '12beac42-4c74-4c3c-8290-8897ccc82e7d' User entered 'No (N)'	System	08 Feb 2021 14:32:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-08T08:32:16', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '12beac42-4c74-4c3c-8290-8897ccc82e7d' User entered '08 Feb 2021 08:32:16'	System	08 Feb 2021 14:32:17
	System	08 Feb 2021 14:32:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '06 Feb 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '10 Feb 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-15T13:20:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cd39e173-152f-436f-807e-2312c4873398'	System	15 Feb 2021 19:20:15
User entered 'No (N)'	System	15 Feb 2021 19:20:15

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-15T13:20:04', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cd39e173-152f-436f-807e-2312c4873398'	System	15 Feb 2021 19:20:15
User entered 'No (N)'	System	15 Feb 2021 19:20:15

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-15T13:20:12', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'cd39e173-152f-436f-807e-2312c4873398'	System	15 Feb 2021 19:20:15
User entered '15 Feb 2021 13:20:12'	System	15 Feb 2021 19:20:15

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '13 Feb 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '17 Feb 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-22T06:54:58', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c32c7777-6f2b-4b02-a640-664b0cfca020' User entered 'No (N)'	System	22 Feb 2021 12:55:18
	System	22 Feb 2021 12:55:18

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-22T06:55:03', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c32c7777-6f2b-4b02-a640-664b0cfca020' User entered 'No (N)'	System	22 Feb 2021 12:55:18
	System	22 Feb 2021 12:55:18

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-02-22T06:55:15', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c32c7777-6f2b-4b02-a640-664b0cfca020' User entered '22 Feb 2021 06:55:15'	System	22 Feb 2021 12:55:18
	System	22 Feb 2021 12:55:18

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '20 Feb 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '24 Feb 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-01T12:01:43-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4f907605-e1de-4d5f-aebf-211d18826f85'	System	01 Mar 2021 18:08:02
User entered 'No (N)'	System	01 Mar 2021 18:08:02

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-01T12:01:47-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4f907605-e1de-4d5f-aebf-211d18826f85'	System	01 Mar 2021 18:08:02
User entered 'No (N)'	System	01 Mar 2021 18:08:02

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-01T12:01:51-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '4f907605-e1de-4d5f-aebf-211d18826f85'	System	01 Mar 2021 18:08:02
User entered '01 Mar 2021 12:01:51'	System	01 Mar 2021 18:08:02

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '27 Feb 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '03 Mar 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-06T08:10:11-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7e92b659-47e0-4620-9f7c-b0b6b4483762'	System	06 Mar 2021 14:10:29
User entered 'No (N)'	System	06 Mar 2021 14:10:29

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-06T08:10:18-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7e92b659-47e0-4620-9f7c-b0b6b4483762'	System	06 Mar 2021 14:10:29
User entered 'No (N)'	System	06 Mar 2021 14:10:29

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-06T08:10:24-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '7e92b659-47e0-4620-9f7c-b0b6b4483762' User entered '06 Mar 2021 08:10:24'	System	06 Mar 2021 14:10:29
	System	06 Mar 2021 14:10:29

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '06 Mar 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '10 Mar 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-15T13:41:18-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '087637c6-8d00-4d00-8b4f-40166db88e63'	System	15 Mar 2021 18:41:33
User entered 'No (N)'	System	15 Mar 2021 18:41:33

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-15T13:41:23-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '087637c6-8d00-4d00-8b4f-40166db88e63'	System	15 Mar 2021 18:41:33
User entered 'No (N)'	System	15 Mar 2021 18:41:33

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-15T13:41:29-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '087637c6-8d00-4d00-8b4f-40166db88e63'	System	15 Mar 2021 18:41:33
User entered '15 Mar 2021 13:41:29'	System	15 Mar 2021 18:41:33

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '13 Mar 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '17 Mar 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-20T07:27:20-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ecd8a1e4-0f21-4d05-938a-5418b0e2983d' User entered 'No (N)'	System	20 Mar 2021 12:27:36
	System	20 Mar 2021 12:27:36

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-20T07:27:27-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ecd8a1e4-0f21-4d05-938a-5418b0e2983d' User entered 'No (N)'	System	20 Mar 2021 12:27:36

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-20T07:27:33-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ecd8a1e4-0f21-4d05-938a-5418b0e2983d' User entered '20 Mar 2021 07:27:33'	System	20 Mar 2021 12:27:36
	System	20 Mar 2021 12:27:36

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '20 Mar 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '24 Mar 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-28T17:07:08-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'df54b908-64c5-4811-8c90-42c909195e19'	System	28 Mar 2021 22:12:23
User entered 'No (N)'	System	28 Mar 2021 22:12:23

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-28T17:07:11-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'df54b908-64c5-4811-8c90-42c909195e19'	System	28 Mar 2021 22:12:23
User entered 'No (N)'	System	28 Mar 2021 22:12:23

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-28T17:07:15-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'df54b908-64c5-4811-8c90-42c909195e19' User entered '28 Mar 2021 17:07:15'	System	28 Mar 2021 22:12:23
	System	28 Mar 2021 22:12:23

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '27 Mar 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '31 Mar 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-05T12:00:35-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae13f38c-d87d-4fdd-81e7-69941507144c' User entered 'No (N)'	System	05 Apr 2021 17:01:44

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-05T12:00:42-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae13f38c-d87d-4fdd-81e7-69941507144c' User entered 'No (N)'	System	05 Apr 2021 17:01:44

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-05T12:00:49-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'ae13f38c-d87d-4fdd-81e7-69941507144c' User entered '05 Apr 2021 12:00:49'	System	05 Apr 2021 17:01:44
	System	05 Apr 2021 17:01:44

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '03 Apr 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '07 Apr 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-12T12:40:45-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0423592b-37d2-4c07-9c46-3e5f7b7a7d8d' User entered 'No (N)'	System	12 Apr 2021 17:40:59
	System	12 Apr 2021 17:40:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-12T12:40:51-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0423592b-37d2-4c07-9c46-3e5f7b7a7d8d' User entered 'No (N)'	System	12 Apr 2021 17:40:59
	System	12 Apr 2021 17:40:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-12T12:40:55-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '0423592b-37d2-4c07-9c46-3e5f7b7a7d8d' User entered '12 Apr 2021 12:40:55'	System	12 Apr 2021 17:40:59
	System	12 Apr 2021 17:40:59

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '10 Apr 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '14 Apr 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-20T12:05:58-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c0624bf7-bca6-4048-bb87-81104891323f' User entered 'No (N)'	System	20 Apr 2021 17:06:38
	System	20 Apr 2021 17:06:38

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-20T12:06:14-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c0624bf7-bca6-4048-bb87-81104891323f' User entered 'No (N)'	System	20 Apr 2021 17:06:38

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-20T12:06:20-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c0624bf7-bca6-4048-bb87-81104891323f' User entered '20 Apr 2021 12:06:20'	System	20 Apr 2021 17:06:38
	System	20 Apr 2021 17:06:38

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '17 Apr 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '21 Apr 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-25T08:00:45-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '82ab8bfa-fed5-4a1b-8019-920fde9fe579'	System	25 Apr 2021 13:01:17
User entered 'No (N)'	System	25 Apr 2021 13:01:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-25T08:00:54-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '82ab8bfa-fed5-4a1b-8019-920fde9fe579'	System	25 Apr 2021 13:01:17
User entered 'No (N)'	System	25 Apr 2021 13:01:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-04-25T08:01:05-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '82ab8bfa-fed5-4a1b-8019-920fde9fe579'	System	25 Apr 2021 13:01:17
User entered '25 Apr 2021 08:01:05'	System	25 Apr 2021 13:01:17

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '24 Apr 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '28 Apr 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-05-03T12:07:23-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '36d19fd3-a553-4d6d-a04a-1d2b7af78151' User entered 'No (N)'	System	03 May 2021 17:12:07
	System	03 May 2021 17:12:07

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

Have you been exposed to someone with 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 (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-05-03T12:07:30-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '36d19fd3-a553-4d6d-a04a-1d2b7af78151'	System	03 May 2021 17:12:07
User entered 'No (N)'	System	03 May 2021 17:12:07

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-05-03T12:07:36-05:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: '36d19fd3-a553-4d6d-a04a-1d2b7af78151'	System	03 May 2021 17:12:07
User entered '03 May 2021 12:07:36'	System	03 May 2021 17:12:07

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '01 May 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '05 May 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '08 May 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '12 May 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '15 May 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '19 May 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '22 May 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '26 May 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '29 May 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '02 Jun 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '05 Jun 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '09 Jun 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '12 Jun 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '16 Jun 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '19 Jun 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '23 Jun 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '26 Jun 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '30 Jun 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '03 Jul 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '07 Jul 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '10 Jul 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '14 Jul 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '17 Jul 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '21 Jul 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '24 Jul 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '28 Jul 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '31 Jul 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '04 Aug 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '07 Aug 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '11 Aug 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '14 Aug 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '18 Aug 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '21 Aug 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '25 Aug 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '28 Aug 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '01 Sep 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '04 Sep 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '08 Sep 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '11 Sep 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '15 Sep 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '18 Sep 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '22 Sep 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '25 Sep 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '29 Sep 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '02 Oct 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '06 Oct 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '09 Oct 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '13 Oct 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '16 Oct 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '20 Oct 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '23 Oct 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '27 Oct 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '30 Oct 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '03 Nov 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '06 Nov 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '10 Nov 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '13 Nov 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '17 Nov 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '20 Nov 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '24 Nov 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '27 Nov 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '01 Dec 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '04 Dec 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '08 Dec 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '11 Dec 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '15 Dec 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '18 Dec 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '22 Dec 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '25 Dec 2021 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '29 Dec 2021 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '01 Jan 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '05 Jan 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '08 Jan 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '12 Jan 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '15 Jan 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '19 Jan 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '22 Jan 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '26 Jan 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '29 Jan 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '02 Feb 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '05 Feb 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '09 Feb 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '12 Feb 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '16 Feb 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '19 Feb 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '23 Feb 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '26 Feb 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '02 Mar 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '05 Mar 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '09 Mar 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '12 Mar 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '16 Mar 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '19 Mar 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '23 Mar 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '26 Mar 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '30 Mar 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '02 Apr 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '06 Apr 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '09 Apr 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '13 Apr 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '16 Apr 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '20 Apr 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '23 Apr 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '27 Apr 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '30 Apr 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '04 May 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '07 May 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '11 May 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '14 May 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '18 May 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '21 May 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '25 May 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '28 May 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '01 Jun 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '04 Jun 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '08 Jun 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '11 Jun 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '15 Jun 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '18 Jun 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '22 Jun 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '25 Jun 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '29 Jun 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '02 Jul 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '06 Jul 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '09 Jul 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '13 Jul 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '16 Jul 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '20 Jul 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '23 Jul 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '27 Jul 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '30 Jul 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '03 Aug 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '06 Aug 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '10 Aug 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '13 Aug 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '17 Aug 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '20 Aug 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '24 Aug 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '27 Aug 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '31 Aug 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '03 Sep 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '07 Sep 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '10 Sep 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '14 Sep 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '17 Sep 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '21 Sep 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '24 Sep 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '28 Sep 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '01 Oct 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '05 Oct 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '08 Oct 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '12 Oct 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '15 Oct 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '19 Oct 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '22 Oct 2022 00:01'	System	19 Nov 2020 23:37:05

US3292236

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:28:29

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 23:37:05
Amendment Manager: User entered '26 Oct 2022 23:59'	System	19 Nov 2020 23:37:05

US3292236

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:28:29

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 22:56:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-01T12:02:17-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c9a31f1d-6ba0-4968-abd4-3941b1499470' User entered 'Yes (Y)'	System	01 Mar 2021 18:10:13
	System	01 Mar 2021 18:10:13

US3292236

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:28:29

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?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:56:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-01T12:02:30-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c9a31f1d-6ba0-4968-abd4-3941b1499470'	System	01 Mar 2021 18:10:13
User entered 'Yes (Y)'	System	01 Mar 2021 18:10:13

US3292236

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:28:29

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 22:56:54
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (5C2E3136-BCAA-4D14-9C74-81D441732E29)', Time: '2021-03-01T12:02:35-06:00', User OID: 'PatientReportedOutcome (US3292236)', ODM File OID: 'c9a31f1d-6ba0-4968-abd4-3941b1499470' User entered '01 Mar 2021 12:02:35'	System	01 Mar 2021 18:10:13
	System	01 Mar 2021 18:10:13

US3292236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
DataPoint Verified.		07 Apr 2021 21:24:04
DataPoint Un-verified.		12 Mar 2021 21:33:57
DataPoint Verified.		12 Mar 2021 21:21:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	17 Dec 2020 14:51:15

US3292236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
DataPoint Verified.		07 Apr 2021 21:24:04
DataPoint Un-verified.		12 Mar 2021 21:33:57
DataPoint Verified.		12 Mar 2021 21:21:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
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) System	17 Dec 2020 14:55:20
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 by data change (Site from System).	System	17 Dec 2020 14:55:20
User entered '12 Nov 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	17 Dec 2020 14:55:20
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	17 Dec 2020 14:51:15
User entered '17 Nov 2020'	(b) (4), (b) (6)	17 Dec 2020 14:51:15

US3292236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
DataPoint Verified.		07 Apr 2021 21:24:04
DataPoint Un-verified.		12 Mar 2021 21:33:57
DataPoint Verified.		12 Mar 2021 21:21:07
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Dec 2020 14:51:15

US3292236

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
DataPoint Verified.		07 Apr 2021 21:24:04
DataPoint Un-verified.		12 Mar 2021 21:33:57
DataPoint Verified.		12 Mar 2021 21:21:07
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Safety call conducted 12 Nov 2020, but no data was input on e-source' reason for change:	(b) (4), (b) (6)	17 Dec 2020 14:55:05
Data Entry Error		
User entered empty.		17 Dec 2020 14:51:15

US3292236

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:24:09
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:55:25

US3292236

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:15
User entered 'l'	System	17 Dec 2020 14:55:25

US3292236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:40:12
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:55:56

US3292236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:40:12
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '16 Dec 2020'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:55:56

US3292236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.	(b) (4)	5 Mar 2021 19:40:12
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4), (b) (6)	17 Dec 2020 14:55:56

US3292236

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		5 Mar 2021 19:40:12
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:55:56

US3292236

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:41:55
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Dec 2020 14:56:10

US3292236

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
User entered 'l'	System	17 Dec 2020 14:56:10

US3292236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:42:52
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:27:40

US3292236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:42:52
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '15 Jan 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:27:40

US3292236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:42:52
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:27:40

US3292236

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	5 Apr 2021 04:34:48
DataPoint Verified.		5 Mar 2021 19:42:52
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:27:40

US3292236

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:43:52
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	18 Jan 2021 20:27:45

US3292236

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
User entered 'l'	System	18 Jan 2021 20:27:45

US3292236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 19:45:17
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Feb 2021 23:17:18

US3292236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:45:17
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '15 Feb 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Feb 2021 23:17:18

US3292236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:45:17
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Feb 2021 23:17:18

US3292236

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:45:17
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Feb 2021 23:17:18

US3292236

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
DataPoint Verified.		15 Mar 2021 19:45:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	16 Feb 2021 23:17:22

US3292236

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:34:48
User entered 'l'	System	16 Feb 2021 23:17:22

US3292236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:13:54
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	18 Mar 2021 18:12:05

US3292236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:13:54
User entered '17 Mar 2021'	Gerardo Pena (b) (4)	18 Mar 2021 18:12:05

US3292236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:13:54
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4)	18 Mar 2021 18:12:05

US3292236

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User entered 'VISIT4'	System	18 Mar 2021 18:12:05

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:45
User entered 'No (N)'		31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:45
User entered empty.		31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:45
User entered empty.		31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User entered empty.	System	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	07 Apr 2021 21:14:45
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:45
User entered empty.		31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	07 Apr 2021 21:14:45
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	07 Apr 2021 21:14:45
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User entered empty.	System	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	07 Apr 2021 21:14:45
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User entered empty.	System	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:14:45
User entered empty.		31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User entered empty.	System	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:45
User entered empty.		31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User entered empty.	System	31 Mar 2021 19:54:17

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16

US3292236

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16

US3292236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:49
User entered 'No (N)'	Gerardo Pena (b) (4)	18 Mar 2021 18:12:16

US3292236

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:14:49
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 18:12:16

US3292236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:15:10
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	18 Mar 2021 18:12:26

US3292236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:15:10
User entered '17 Mar 2021'	Gerardo Pena (b) (4)	18 Mar 2021 18:12:26

US3292236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:15:10
User entered '10:29'	Gerardo Pena (b) (4)	18 Mar 2021 18:12:26

US3292236

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User entered '17 Mar 2021 10:29'	System	18 Mar 2021 18:12:26

US3292236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:15:15
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	18 Mar 2021 18:12:30

US3292236

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:04:16
User entered 'I'	System	18 Mar 2021 18:12:30

US3292236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:48:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:12:18

US3292236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:48:35
User entered '16 Apr 2021'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:12:18

US3292236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:48:35
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:12:41
User entered 'Contact Made (CONTACT MADE)'		19 Apr 2021 15:12:18

US3292236

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:48:35
	(b) (4)	
User entered '3 attempts no answer' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Apr 2021 15:12:41
User entered empty.		19 Apr 2021 15:12:18

US3292236

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:48:35
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Apr 2021 15:12:22

US3292236

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Apr 2021 15:12:22

US3292236

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

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:10:39

US3292236

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

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:10:39

US3292236

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

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Clinic (Clinic)'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:10:39

US3292236

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

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'UNBLND_DECIDE'	System	12 Jan 2021 21:10:39

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:06

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:57:24

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:06

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 05:57:24

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:06
	(b) (4)	

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Placebo (Placebo)'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:06

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:27:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 02:49:03
User entered 'Placebo (Placebo)'	Victoria Hernandez (b) (4)	12 Jan 2021 21:12:06
	(b) (4)	

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Amendment Manager: User entered 'Placebo (Placebo)'	(b) (4) System	20 Jan 2021 02:49:03
User entered 'Placebo (Placebo)'	Victoria Hernandez (b) (4)	12 Jan 2021 21:12:06
	(b) (4)	

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:06

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'I'	System	12 Jan 2021 21:12:06

US3292236

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

Form: Unblinding

Generated On: 09 Jun 2021 16:28:29

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'I'	System	12 Jan 2021 21:12:06

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered missing code ND - Not Done.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:22
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered missing code ND - Not Done.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered empty.	System	13 Jan 2021 16:40:02
DataPoint set to visible.	System	12 Jan 2021 21:12:06

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered missing code ND - Not Done.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:22
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered missing code ND - Not Done.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered empty.	System	13 Jan 2021 16:40:02
DataPoint set to visible.	System	12 Jan 2021 21:12:06

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User accepted default value 'Pre-Dose (PREDOSE)'	Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '10:36'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered '12 Jan 2021 10:36'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '36.4' C	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Oral (Oral)'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4)	
	Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '70'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'bpm'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '17'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'breaths/min'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '100'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'mmHg'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4)	07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 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)	21 Jan 2021 08:21:48
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Gerardo Pena (b) (4) (b) (4)	19 Jan 2021 18:39:15
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		13 Jan 2021 16:40:02
User entered '59'	Victoria Hernandez (b) (4) (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'mmHg'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:20
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered missing code ND - Not Done.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:27:22
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered missing code ND - Not Done.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:28:29

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered empty.	System	13 Jan 2021 16:40:02
DataPoint set to visible.	System	12 Jan 2021 21:12:06

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User accepted default value 'Post-Dose (POSTDOSE)'	Victoria Hernandez (b) (4) (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12:15'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered '12 Jan 2021 12:15'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '36.3' C	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Oral (Oral)'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '68'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02
	(b) (4)	

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'bpm'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '16'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'breaths/min'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '118'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'mmHg'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:28:14
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Jan 2021 08:22:02
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).	Gerardo Pena (b) (4)	19 Jan 2021 18:40:02
User opened query 'Diastolic Blood Pressure reported System is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).		13 Jan 2021 16:40:02
User entered '55'	Victoria Hernandez (b) (4)	13 Jan 2021 16:40:02

US3292236

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

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'mmHg'	System	13 Jan 2021 16:40:02

US3292236

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:28:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:45:15

US3292236

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

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:28:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:45:15

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:45:40

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:45:40

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:45:40

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'mRNA-1273'	System	13 Jan 2021 16:45:40
DataPoint set to visible.	System	12 Jan 2021 21:12:06

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:45:40
	(b) (4)	

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '11:45'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:45:40

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered '12 Jan 2021 11:45'	System	13 Jan 2021 16:45:40

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:29:02
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) Victoria Hernandez (b) (4) (b) (4)	13 Jan 2021 16:45:40

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:02
User entered 'ONCE'	System	13 Jan 2021 16:45:40

US3292236

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

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'INTRAMUSCULAR'	System	13 Jan 2021 16:45:40

US3292236

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:28

US3292236

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:28
	(b) (4)	

US3292236

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4)	07 Apr 2021 21:29:31
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '10:40' reason for change: Data Entry Error	System	12 Jan 2021 21:12:36
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Victoria Hernandez (b) (4)	12 Jan 2021 21:12:36
User entered '10:60' (non-conformant).	(b) (4)	
	System	12 Jan 2021 21:12:28
	Victoria Hernandez (b) (4)	12 Jan 2021 21:12:28
	(b) (4)	

US3292236

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered '12 Jan 2021 10:40'	System	12 Jan 2021 21:12:36
User entered '12 Jan 2021 10:60' (non-conformant).	System	12 Jan 2021 21:12:28

US3292236

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:47

US3292236

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '12 Jan 2021'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:47

US3292236

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:37
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '11:05'	(b) (4) Victoria Hernandez (b) (4)	12 Jan 2021 21:12:47

US3292236

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:28:29

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered '12 Jan 2021 11:05'	System	12 Jan 2021 21:12:47

US3292236

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

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:29:41
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Victoria Hernandez (b) (4)	13 Jan 2021 16:45:45

US3292236

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

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'I'	System	13 Jan 2021 16:45:45

US3292236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		05 Mar 2021 15:36:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Jan 2021 17:59:22

US3292236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 15:36:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '19 Jan 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Jan 2021 17:59:22

US3292236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		05 Mar 2021 15:36:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Jan 2021 17:59:22

US3292236

Folder: Safety Call OL-D8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4)	05 Mar 2021 15:36:54
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Jan 2021 17:59:22

US3292236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		07 Apr 2021 21:23:38
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Jan 2021 17:59:30

US3292236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'l'	System	22 Jan 2021 17:59:30

US3292236

Folder: Safety Call OL-D8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[OLD29 Placebo Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'I'	System	22 Jan 2021 17:59:30
DataPoint set to visible.	System	22 Jan 2021 17:59:30

US3292236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:30:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:52:45

US3292236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:30:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:52:45

US3292236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:30:23
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:52:45

US3292236

Folder: OL-D29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'OLD29'	System	09 Feb 2021 19:52:45

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User accepted default value 'Pre-Dose (PREDOSE)'		09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4)	07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '9 Feb 2021'	(b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '10:16'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered '9 Feb 2021 10:16'	System	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '36.3' C	(b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4)	07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered empty.	(b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '74'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'bpm'	System	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '16'	(b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'breaths/min'	System	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '106'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'mmHg'	System	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User closed query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	26 Feb 2021 12:49:02
Query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'ncs' (Site from System).	(b) (4), (b) (6)	25 Feb 2021 17:54:10
User opened query 'Diastolic Blood Pressure reported is out of range < 60 or > 110 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	09 Feb 2021 19:53:48
User entered '53'	(b) (4), (b) (6)	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'mmHg'	System	09 Feb 2021 19:53:48

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User accepted default value 'Post-Dose (POSTDOSE)'	(b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '11:40'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered '9 Feb 2021 11:40'	System	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '37.5' C	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '67'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'bpm'	System	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '16'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'breaths/min'	System	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '105'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'mmHg'	System	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:31:12
User signature succeeded.	Douglas Denham (b) (4)	03 Mar 2021 14:15:54
User entered '60'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'mmHg'	System	09 Feb 2021 19:58:58

US3292236

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:24
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Feb 2021 19:59:23

US3292236

Folder: OL-D29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:31:24
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:59:23

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:32:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:32:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:32:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the study treatment? \(Unblinded\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'mRNA-1273'	System	09 Feb 2021 19:59:37
DataPoint set to visible.	System	22 Jan 2021 17:59:30

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:32:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '9 Feb 2021'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:32:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '11:08'	(b) (4), (b) (6)	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered '9 Feb 2021 11:08'	System	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.	(b) (4)	07 Apr 2021 21:32:01
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:32:01
User entered 'ONCE'	System	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:28:29

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'INTRAMUSCULAR'	System	09 Feb 2021 19:59:37

US3292236

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
DataPoint Verified.		07 Apr 2021 21:32:06
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	09 Feb 2021 19:59:40

US3292236

Folder: OL-D29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'l'	System	09 Feb 2021 19:59:40

US3292236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4)	05 Mar 2021 15:38:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 03:35:49
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	15 Feb 2021 12:12:12
Query 'Data is required. Please complete.' answered with 'data entered for wrong subject.' (Site from System).	Gerardo Pena (b) (4)	12 Feb 2021 21:25:28
User opened query 'Data is required. Please complete.' (Site from System).	System	12 Feb 2021 21:25:15
User entered empty; reason for change Data Entry Error	Gerardo Pena (b) (4)	12 Feb 2021 21:25:15
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	12 Feb 2021 21:10:12

US3292236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4)	05 Mar 2021 15:38:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '17 Feb 2021' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 03:35:49
User entered empty; reason for change Data Entry Error	Gerardo Pena (b) (4)	12 Feb 2021 21:25:15
User entered '11 Feb 2021'	Gerardo Pena (b) (4)	12 Feb 2021 21:10:12

US3292236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.	(b) (4)	05 Mar 2021 15:38:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Contact Made (CONTACT MADE)' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Feb 2021 03:35:49
User entered empty; reason for change Data Entry Error	Gerardo Pena (b) (4)	12 Feb 2021 21:25:15
User entered 'Contact Made (CONTACT MADE)'	Gerardo Pena (b) (4)	12 Feb 2021 21:10:12

US3292236

Folder: Safety Call OL-D36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:28:29

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		05 Mar 2021 15:38:15
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	12 Feb 2021 21:10:12

US3292236

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
DataPoint Verified.		05 Mar 2021 15:38:21
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	18 Feb 2021 03:35:54

US3292236

Folder: Safety Call OL-D36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:28:29

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:44
User entered 'l'	System	18 Feb 2021 03:35:54

US3292236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:33:43
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	18 Mar 2021 17:52:31

US3292236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:33:43
User entered '11 Mar 2021'	Gerardo Pena (b) (4)	18 Mar 2021 17:52:31

US3292236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:33:43
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4)	18 Mar 2021 17:52:31

US3292236

Folder: OL-D57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:28:29

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered 'OLD57'	System	18 Mar 2021 17:52:31

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered 'No (N)'	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered empty.	System	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered empty.	System	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered empty.	System	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered empty.	System	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:02
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered empty.	System	18 Mar 2021 17:52:38

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40

US3292236

Folder: OL-D57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:28:29

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40

US3292236

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:04
User entered 'No (N)'	Gerardo Pena (b) (4)	18 Mar 2021 17:52:43

US3292236

Folder: OL-D57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:28:29

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:04
User entered empty.	Gerardo Pena (b) (4)	18 Mar 2021 17:52:43

US3292236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:12
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	18 Mar 2021 17:53:01

US3292236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:12
User entered '11 Mar 2021'	Gerardo Pena (b) (4)	18 Mar 2021 17:53:01

US3292236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:34:12
User entered '08:48'	Gerardo Pena (b) (4)	18 Mar 2021 17:53:01

US3292236

Folder: OL-D57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:28:29

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 11:39:40
User entered '11 Mar 2021 08:48'	System	18 Mar 2021 17:53:01

US3292236

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:28:29

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:25
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User closed query 'The subject reported nausea secondary to a migraine on the Day 43 Safety Call. Please consider adding as an AE if appropriate.' (Site from CRA).	(b) (4), (b) (6)	22 Mar 2021 20:09:47
User closed query 'Diagnosis of Nausea was listed on Discharge Summary. Please confirm and consider updating AE log.' (Site from CRA).		22 Mar 2021 20:09:46
User closed query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating AE log.' (Site from CRA).		22 Mar 2021 20:09:44
Query 'The subject reported nausea secondary to a migraine on the Day 43 Safety Call. Please consider adding as an AE if appropriate.' answered with 'Nausea is a symptom of diagnosed migraines. AE not required.' (Site from CRA).		13 Jan 2021 22:05:42
Query 'Diagnosis of Nausea was listed on Discharge Summary. Please confirm and consider updating AE log.' answered with 'Nausea is a symptom of diagnosed migraine. AE not required.' (Site from CRA).		13 Jan 2021 22:05:08
Query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating AE log' answered with 'Vertigo was added' (Site from CRA).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:13:41
User opened query 'The subject reported nausea secondary to a migraine on the Day 43 Safety Call. Please consider adding as an AE if appropriate.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:51:43
User opened query 'Diagnosis of Nausea was listed on Discharge Summary. Please confirm and consider updating AE log.' (Site from CRA).		23 Oct 2020 19:55:11
User opened query 'Diagnosis of Vertigo was listed on Discharge Summary. Please confirm and consider updating AE log.' (Site from CRA).		23 Oct 2020 19:54:53
DataPoint Verified.		01 Oct 2020 18:16:01
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Sep 2020 13:44:55

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
Reviewed for Safety.		10 Sep 2020 17:25:35
User entered 'USA-US072-2020-mRNA-1273-P301000001'	System	10 Sep 2020 17:22:57
User entered 'New'	(b) (4), (b) (6)	10 Sep 2020 17:22:57

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User closed query 'PV Query: Please confirm if the reported "possible fibromuscular dysplasia" was considered an SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).		22 Sep 2020 14:48:42
User closed query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. Please update as applicable.' (Site from Safety).		22 Sep 2020 14:48:33
User closed query 'PV Query: Please confirm the sex of the subject as Medical History of uterine fibroids and hysterectomy does not coincide with a male subject and reconcile accordingly.' (Site from Safety).		22 Sep 2020 14:47:00
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Fibromuscular dysplasia, LLT: Fibromuscular dysplasia - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 22:56:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	21 Sep 2020 22:56:46
Query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. Please update as applicable.' answered with 'updated' (Site from Safety).	Kevin Martinez (b) (4)	21 Sep 2020 22:56:24
Query 'PV Query: Please confirm if the reported "possible fibromuscular dysplasia" was considered an SAE. If yes, please provide missing seriousness criteria as soon as possible.' answered with 'updated' (Site from Safety).	Kevin Martinez (b) (4)	21 Sep 2020 22:56:18
Data point term sent to Coder	System	21 Sep 2020 22:55:43
Coding entries removed.	Kevin Martinez (b) (4)	21 Sep 2020 22:54:48

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Fibromuscular Dysplasia' reason for change: Data Entry Error	Kevin Martinez (b) (4)	21 Sep 2020 22:54:48
Query 'PV Query: Please confirm the sex of the subject as Medical History of uterine fibroids and hysterectomy does not coincide with a male subject and reconcile accordingly.' answered with 'UPDATED' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please consider updating the event term to the underlying cause/etiology of the event. Please update as applicable.' (Site from Safety).	Victoria Hernandez (b) (4)	21 Sep 2020 22:07:21
User opened query 'PV Query: Please confirm if the reported "possible fibromuscular dysplasia" was considered an SAE. If yes, please provide missing seriousness criteria as soon as possible.' (Site from Safety).	(b) (4)	
User opened query 'PV Query: Please confirm the sex of the subject as Medical History of uterine fibroids and hysterectomy does not coincide with a male subject and reconcile accordingly.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:40:06
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\23.0.		16 Sep 2020 19:39:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.		16 Sep 2020 19:38:26
Data point term sent to Coder		
User entered 'Dizziness, nausea secondary to the dizziness.'		
User coded data point as SOC: Nervous system disorders, HLGT: Neurological disorders NEC, HLT: Neurological signs and symptoms NEC, PT: Dizziness, LLT: Dizziness - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 13:54:39
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	(b) (4)	
Data point term sent to Coder	Coder Import (b) (4)	11 Sep 2020 13:54:39
User entered 'Dizziness, nausea secondary to the dizziness.'	System	09 Sep 2020 14:17:25
	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered 'No (N)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered 'No (N)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:42:32
User closed query 'Start Date in source is listed as 04SEP2020. Please reconcile.' (Site from CRA).		06 Nov 2020 15:42:18
Query 'Start Date in source is listed as 04SEP2020. Please reconcile.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	04 Nov 2020 16:19:20
User entered '4 Sep 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	04 Nov 2020 16:19:13
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 18:19:00
User opened query 'Start Date in source is listed as 04SEP2020. Please reconcile.' (Site from CRA).		21 Oct 2020 18:18:48
DataPoint Verified.		01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '3 Sep 2020'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 15:42:34
User closed query 'Per source, start time is 7:30. Please confirm/update.' (Site from CRA).		06 Nov 2020 15:42:30
Query 'Per source, start time is 7:30. Please confirm/update.' answered with 'no time required as per system query that states "[] Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.'" (Site from CRA).	Antonio Gutierrez (b) (4)	05 Nov 2020 23:04:10
User closed query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Nov 2020 23:03:42
User entered empty; reason for change Per Query Resolution	Antonio Gutierrez (b) (4)	05 Nov 2020 23:03:42
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	05 Nov 2020 23:02:50
User entered '07:30' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	05 Nov 2020 23:02:50
User opened query 'Per source, start time is 7:30. Please confirm/update.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:21:46
DataPoint Un-verified.		21 Oct 2020 18:19:02
DataPoint Verified.		01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered empty.	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 23:03:42
User entered '4 Sep 2020 07:30'	System	05 Nov 2020 23:02:50
User entered empty.	System	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered 'No (N)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '5 Sep 2020'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	06 Nov 2020 16:07:59
User closed query 'End time per source was 1300. Please update/confirm.' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 16:07:55
User closed query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Nov 2020 23:05:15
User entered empty; reason for change Per Query Resolution	Antonio Gutierrez (b) (4)	05 Nov 2020 23:05:15
Query 'End time per source was 1300. Please update/confirm.' answered with 'No time required as per system query that states "End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time."' (Site from CRA).	Antonio Gutierrez (b) (4)	05 Nov 2020 23:04:58
User opened query 'End time is present for an AE that did not start within 24 hours after dosing. Please remove the End time.' (Site from System).	System	05 Nov 2020 23:02:50
User entered '13:00' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	05 Nov 2020 23:02:50
User opened query 'End time per source was 1300. Please update/confirm.' (Site from CRA).	(b) (4), (b) (6)	21 Oct 2020 18:22:16
DataPoint Un-verified.		21 Oct 2020 18:21:55
DataPoint Verified.		01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered empty.	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Nov 2020 23:05:15
User entered '5 Sep 2020 13:00'	System	05 Nov 2020 23:02:50
User entered empty.	System	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:09
User closed query 'PV Query: The event intensity is "Grade 4" for this event of dizziness, nausea secondary to the dizziness. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	22 Sep 2020 14:48:48
Query 'PV Query: The event intensity is "Grade 4" for this event of dizziness, nausea secondary to the dizziness. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' answered with 'entry error, updated' (Site from Safety).	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:54:34
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:41:55
User opened query 'PV Query: The event intensity is "Grade 4" for this event of dizziness, nausea secondary to the dizziness. Per the vaccine grading (Grade 4=potential life-threatening). Please include "life-threatening" as an additional seriousness criterion or please reassess the event intensity grade, and update as applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:40:36
User entered 'Grade 4 (Grade 4)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '0'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '0'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).		22 Sep 2020 14:48:55
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'patient was admitted from 04Sep2020 till 05Sep2020' (Site from Safety).	Kevin Martinez (b) (4)	21 Sep 2020 22:49:16
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	16 Sep 2020 19:40:22
	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '4 Sep 2020'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		25 Sep 2020 16:48:27
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'Discharge summary sent today, 24SEP2020 by AG.' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Sep 2020 22:03:44
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:38:41
User entered '5 Sep 2020'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:09
User entered 'No (N)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:09
User entered empty.	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '0'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '0'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '0'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25
	(b) (4)	

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:09
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:09
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:43:47
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:18:49
User entered '1' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	10 Mar 2021 19:22:53
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 12:15:57
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	16 Feb 2021 23:19:29
User entered '0' reason for change: Per Query Resolution	Gerardo Pena (b) (4) (b) (4)	16 Feb 2021 23:19:20
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:02:21
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Nov 2020 22:24:40
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:24:40
User entered '1' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:24:40
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	24 Nov 2020 22:24:03

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered '0'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 20:43:50
User closed query 'Per source, Other action taken is "Concomitant Medication". Please review and reconcile.' (Site from CRA). User signature succeeded.	(b) (4)	16 Apr 2021 20:43:48
Query 'Per source, Other action taken is "Concomitant Medication". Please review and reconcile.' answered with 'updated' (Site from CRA).	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User opened query 'Per source, Other action taken is "Concomitant Medication". Please review and reconcile.' (Site from CRA).	(b) (4)	
User closed query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no CM recorded that matches this AE 'FIBROMUSCULAR DYSPLASIA' during this timeframe? Please review and add a Con Med as appropriate or update action taken. If CM is already recorded, please provide log line number ensuring indication matches with this event.' (Site from DM).	Antonio Gutierrez (b) (4)	13 Apr 2021 15:20:09
Query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no CM recorded that matches this AE 'FIBROMUSCULAR DYSPLASIA' during this timeframe? Please review and add a Con Med as appropriate or update action taken. If CM is already recorded, please provide log line number ensuring indication matches with this event.'	(b) (4), (b) (6)	07 Apr 2021 21:11:52
answered with 'updated' (Site from DM).		
User entered '0' reason for change: Per Query Resolution	(b) (4)	11 Mar 2021 08:52:04
User opened query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no CM recorded that matches this AE 'FIBROMUSCULAR DYSPLASIA' during this timeframe? Please review and add a Con Med as appropriate or update action taken. If CM is already recorded, please provide log line number ensuring indication matches with this event.'	Antonio Gutierrez (b) (4)	10 Mar 2021 19:23:01
answered with 'updated' (Site from DM).		
User entered '0' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	10 Mar 2021 19:22:53
User opened query 'Per CDM: Other Action Taken = Concomitant Medication, however there is no CM recorded that matches this AE 'FIBROMUSCULAR DYSPLASIA' during this timeframe? Please review and add a Con Med as appropriate or update action taken. If CM is already recorded, please provide log line number ensuring indication matches with this event.'	(b) (4), (b) (6)	17 Feb 2021 12:19:11
answered with 'updated' (Site from DM).		
User entered '1' reason for change: Per Query Resolution	Gerardo Pena (b) (4)	16 Feb 2021 23:19:20
	(b) (4)	

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, MECLIZINE is indicated for "VERTIGO" and not for this AE. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:53:34
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, MECLIZINE is indicated for "VERTIGO" and not for this AE. Please review and add a Con Medication as appropriate or update action taken' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:21:06
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:20:54
User entered '0' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:20:54
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, MECLIZINE is indicated for "VERTIGO" and not for this AE. Please review and add a Con Medication as appropriate or update action taken' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:15:17
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		09 Nov 2020 14:35:44
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Meclizine added' (Site from DM).	Antonio Gutierrez (b) (4)	05 Nov 2020 23:15:41
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Nov 2020 08:50:36
DataPoint Verified.		01 Oct 2020 18:16:21

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User closed query 'PV Query: Please confirm if Aimovig (prescribed on 21 Aug 2020) should be added as concomitant medication.' (Site from Safety).		22 Sep 2020 14:49:08
User entered '1' reason for change: Data Entry Error	Kevin Martinez (b) (4)	21 Sep 2020 22:39:14
Query 'PV Query: Please confirm if Aimovig (prescribed on 21 Aug 2020) should be added as concomitant medication.' answered with 'updated in concomitant medication' (Site from Safety).	(b) (4) Kevin Martinez (b) (4)	21 Sep 2020 22:38:47
User opened query 'PV Query: Please confirm if Aimovig (prescribed on 21 Aug 2020) should be added as concomitant medication.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:41:11
User entered '0'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:11:57
User closed query 'Per DM CLR: RQ: Response noted, however, it was ticked back again. Procedures recorded are diagnostic procedures. Only therapeutic procedures are accepted for this to be ticked. Update as appropriate. Otherwise, clarify.' (Site from DM).		11 Mar 2021 08:51:14
User entered '0' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	10 Mar 2021 19:10:17
Query 'Per DM CLR: RQ: Response noted, however, it was ticked back again. Procedures recorded are diagnostic procedures. Only therapeutic procedures are accepted for this to be ticked. Update as appropriate. Otherwise, clarify.' answered with '10MAR21 - will remove this tick mark as well as remove from paper source.' (Site from DM).	Antonio Gutierrez (b) (4)	10 Mar 2021 19:10:03
User opened query 'Per DM CLR: RQ: Response noted, however, it was ticked back again. Procedures recorded are diagnostic procedures. Only therapeutic procedures are accepted for this to be ticked. Update as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 04:43:35
User entered '1' reason for change: Per Query Resolution	Gerardo Pena (b) (4)	16 Feb 2021 23:19:20
User closed query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	25 Nov 2020 14:53:58
Query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' answered with 'updated as per query' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:24:50
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	24 Nov 2020 22:24:03
User entered '0' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:24:03

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Con Proc, however the recorded Concomitant Procedure is a Diagnostic procedure and not a Medical Treatment Procedure. Please review and record a Medical Treatment Procedure as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:17:28
User closed query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	(b) (4), (b) (6)	09 Nov 2020 14:35:46
(Site from DM).	(b) (4), (b) (6)	
User closed query 'MRA and MRI were mentioned in hospital discharge summary. Please consider updating Con Procedure page if found appropriate.'	(b) (4), (b) (6)	06 Nov 2020 18:19:19
(Site from CRA).	(b) (4), (b) (6)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:19:13
Query 'MRA and MRI were mentioned in hospital discharge summary. Please consider updating Con Procedure page if found appropriate.' answered with 'will update' (Site from CRA).	Antonio Gutierrez (b) (4)	05 Nov 2020 23:51:33
User entered '1' reason for change: New Information	Antonio Gutierrez (b) (4)	05 Nov 2020 23:51:14
User opened query 'MRA and MRI were mentioned in hospital discharge summary. Please consider updating Con Procedure page if found appropriate.'	(b) (4), (b) (6)	21 Oct 2020 18:39:45
(Site from CRA).	(b) (4), (b) (6)	
Query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken.'	Victoria Hernandez (b) (4)	13 Oct 2020 20:42:21
'answered with 'updated' (Site from DM).	(b) (4)	
DataPoint Un-verified.	Victoria Hernandez (b) (4)	13 Oct 2020 20:42:13
User entered '0' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	13 Oct 2020 20:42:13
	(b) (4)	

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Treatment Required = Con Procedure, however there is no Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Procedure as appropriate or update action taken. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Oct 2020 23:55:56
DataPoint Un-verified.		01 Oct 2020 18:16:21
DataPoint Verified.		01 Oct 2020 18:16:15
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		01 Oct 2020 18:16:09
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'No medication treatments given during hospitalization.' (Site from Safety).	Kevin Martinez (b) (4)	22 Sep 2020 14:49:14
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	21 Sep 2020 22:54:15
User entered 'I'	Antonio Gutierrez (b) (4)	16 Sep 2020 19:39:10

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	01 Oct 2020 18:16:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User entered empty.	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User closed query 'Per DM CLR: Narrative indicates that the subject experienced Nausea. However, there is no recorded AE that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:21:50
User closed query 'Per DM CLR: Narrative indicates that the subject was given an unrecalled meds for nausea. However, there is no recorded ConMed that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).		16 Apr 2021 09:21:45
Query 'Per DM CLR: Narrative indicates that the subject was given an unrecalled meds for nausea. However, there is no recorded ConMed that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' answered with 'As per patient, medical records, and discharge summary, no medications are listed for nausea. patient may have been referring to another medication already in med log. ' (Site from DM).	Antonio Gutierrez (b) (4)	13 Apr 2021 15:44:03
Query 'Per DM CLR: Narrative indicates that the subject experienced Nausea. However, there is no recorded AE that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' answered with 'As per medical records and hospital discharge summary, no medications were reported for "nausea". Patient cannot recall and may have been referring to different medication already noted in Med log. ' (Site from DM).	Antonio Gutierrez (b) (4)	13 Apr 2021 15:43:00
User opened query 'Per DM CLR: Narrative indicates that the subject was given an unrecalled meds for nausea. However, there is no recorded ConMed that match the information. Please update to record the corresponding ConMed as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:50:01

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Narrative indicates that the subject experienced Nausea. However, there is no recorded AE that match the information. Please update to record the corresponding AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 12:49:49
User closed query 'PV Query: Please clarify whether the subjected received the second IP administration.' (Site from Safety).		25 Nov 2020 18:05:45
User closed query 'Per DM CLR: SAE Narrative = PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN". Please confirm if these tests were followed up and verified. If yes, please ensure that these were captured in the appropriate eCRF. Otherwise, clarify.' (Site from DM).		25 Nov 2020 16:33:38
User closed query 'Per DM CLR: SAE Narrative = EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. Please confirm if this medication was followed up and verified. If yes, please ensure that this is captured in the appropriate eCRF. Otherwise, clarify.' (Site from DM).		25 Nov 2020 16:33:32
Query 'Per DM CLR: SAE Narrative = PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN". Please confirm if these tests were followed up and verified. If yes, please ensure that these were captured in the appropriate eCRF. Otherwise, clarify.' answered with 'all tests based on medical records request have been reconciled. Diagnostic tests noted ' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:28:50
Query 'Per DM CLR: SAE Narrative = EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. Please confirm if this medication was followed up and verified. If yes, please ensure that this is captured in the appropriate eCRF. Otherwise, clarify.' answered with 'It was followed up, but medication is unknown' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:28:01
Query 'PV Query: Please clarify whether the subjected received the second IP administration.' answered with 'Second IP administration received 17SEP2020' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:27:31

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: SAE Narrative = PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN". Please confirm if these tests were followed up and verified. If yes, please ensure that these were captured in the appropriate eCRF. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:12:23
User opened query 'Per DM CLR: SAE Narrative = EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. Please confirm if this medication was followed up and verified. If yes, please ensure that this is captured in the appropriate eCRF. Otherwise, clarify.' (Site from DM).		23 Nov 2020 23:12:14
User opened query 'PV Query: Please clarify whether the subjected received the second IP administration.' (Site from Safety).		13 Nov 2020 16:37:10
DataPoint Verified.		06 Nov 2020 16:18:27
User closed query 'Per AE log in source, recorded by date was 17SEP2020 and Date AE reported was 19SEP2020. Please reconcile.' (Site from CRA).		06 Nov 2020 16:18:23
Query 'Per AE log in source, recorded by date was 17SEP2020 and Date AE reported was 19SEP2020. Please reconcile.' answered with 'These dates are erroneous. Will correct as per documentation in electronic source documents' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 23:36:40
User opened query 'Per AE log in source, recorded by date was 17SEP2020 and Date AE reported was 19SEP2020. Please reconcile.' (Site from CRA).		21 Oct 2020 18:25:07
DataPoint Un-verified.		21 Oct 2020 18:24:22
DataPoint Verified.		01 Oct 2020 18:16:21
DataPoint Un-verified.		01 Oct 2020 18:16:15
DataPoint Verified.		01 Oct 2020 18:16:09
User closed query 'PV Query: It was reported that the subject underwent an MRI, please provide test results and any other relevant laboratory and diagnostic test results (including Covid testing). Please include units and reference ranges if applicable.' (Site from Safety).		25 Sep 2020 16:48:33

PRODUCTION RELEASE (v12.003
EAB) (1725)

1921 of 2333

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: It was reported that the subject underwent an MRI, please provide test results and any other relevant laboratory and diagnostic test results (including Covid testing). Please include units and reference ranges if applicable.' answered with 'Narrative has been updated with requested information' (Site from Safety).	Antonio Gutierrez (b) (4)	24 Sep 2020 22:09:56
User entered 'THIS REPORT IS FOLLOWING PATIENT'S INITIAL REPORT TO STAFF ON THE MORNING OF 09SEP2020. PT RECEIVED FIRST IP INJECTION ON 20AUG2020. ON 21ST, PT HAD APPOINTMENT WITH DOCTOR FOR MIGRAINES. DOCTOR PRESCRIBED AIMOVIG, WHICH PT STARTED IMMEDIATELY. ON 03SEP, PT WAS "NOT FEELING NORMAL". SHE COULD NOT DESCRIBE HER SYMPTOMS, SIMPLY STATING SHE WAS NOT FEELING NORMAL. ON 04SEP PT STATES SHE WOKE UP TO THE ROOM SPINNING, SHE WAS EXPERIENCING NAUSEA, AND CALLED AN AMBULANCE. WHILE IN THE AMBULANCE, EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. WHILE IN THE ER, PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN", BUT COULD NOT FIND ANYTHING ABNORMAL. DOCTORS DECIDED TO CONDUCT MRI WITH CONTRAST. ACCORDING TO PATIENT, SHE WAS TOLD BY HER DOCTOR THAT SHE HAD "POSSIBLE FIBROMUSCULAR DYSPLASIA". AT THIS TIME, PT WAS UNABLE TO PROVIDE ANY FURTHER INFORMATION. WE WILL REQUEST MEDICAL RECORDS FROM HOSPITAL ASAP.	Antonio Gutierrez (b) (4)	24 Sep 2020 22:09:47
UPDATE: Discharge summary sent to Safety 24SEP2020. States "MRI findings of beading in distal cervical arteries suggested possible fibromuscular dysplasia." D/c summary also states that patient is to follow up with Neurologist to discuss these findings. No further information or lab results given. COVID testing not mentioned. Please review report.' reason for change: Data Entry Error		

PRODUCTION RELEASE (v12.003
EAB) (1725)

1922 of 2333

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: It was reported that the subject underwent an MRI, please provide test results and any other relevant laboratory and diagnostic test results (including Covid testing). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	16 Sep 2020 19:38:58
User entered 'This report is following patient's initial report to staff on the morning of 09SEP2020. PT RECEIVED FIRST IP INJECTION ON 20AUG2020. ON 21ST, PT HAD APPOINTMENT WITH DOCTOR FOR MIGRAINES. DOCTOR PRESCRIBED AIMOVIG, WHICH PT STARTED IMMEDIATELY. ON 03SEP, PT WAS "NOT FEELING NORMAL". SHE COULD NOT DESCRIBE HER SYMPTOMS, SIMPLY STATING SHE WAS NOT FEELING NORMAL. ON 04SEP PT STATES SHE WOKE UP TO THE ROOM SPINNING, SHE WAS EXPERIENCING NAUSEA, AND CALLED AN AMBULANCE. WHILE IN THE AMBULANCE, EMT GAVE PT SOMETHING FOR NAUSEA, THOUGH PT CANNOT RECALL WHAT IT WAS. WHILE IN THE ER, PT STATES DOCTORS DID "EVERY TEST KNOWN TO MAN", BUT COULD NOT FIND ANYTHING ABNORMAL. DOCTORS DECIDED TO CONDUCT MRI WITH CONTRAST. ACCORDING TO PATIENT, SHE WAS TOLD BY HER DOCTOR THAT SHE HAD "POSSIBLE FIBROMUSCULAR DYSPLASIA". AT THIS TIME, PT WAS UNABLE TO PROVIDE ANY FURTHER INFORMATION. WE WILL REQUEST MEDICAL RECORDS FROM HOSPITAL ASAP.' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	09 Sep 2020 15:51:56

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Pt received first IP injection on 20AUG2020. On 21st, pt had appointment with doctor for migraines. Doctor prescribed AIMOVIG, which pt started immediately. On 03SEP, pt was "not feeling normal". She could not describe her symptoms, simply stating she was not feeling normal. On 04SEP pt states she woke up to the room spinning, she was experiencing nausea, and called an ambulance. While in the ambulance, EMT gave pt something for nausea, though pt cannot recall what it was. While in the ER, pt states doctors did "every test known to man", but could not find anything abnormal. Doctors decided to conduct MRI with contrast. According to patient, she was told by her doctor that she had "possible fibromuscular dysplasia". At this time, pt was unable to provide any further information. We will request medical records from hospital asap.'	Antonio Gutierrez (b) (4)	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'l'	System	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:28:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Sep 2020 14:17:25

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User coded data point as SOC: Ear and labyrinth disorders, HLG: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:17:39
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:17:39
Data point term sent to Coder	System	10 Nov 2020 00:17:15
User entered 'Vertigo'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'No (N)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'No (N)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '3 Sep 2020' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	24 Nov 2020 22:32:33
User entered '3 Nov 2020'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User entered empty.	System	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).		17 Feb 2021 12:20:28
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4)	16 Feb 2021 23:22:15
User entered 'No (N)' reason for change: New Information	(b) (4)	
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	08 Dec 2020 06:03:23
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '4 Sep 2020' reason for change: New Information	Gerardo Pena (b) (4)	16 Feb 2021 23:22:05
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User entered empty.	System	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'No (N)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'None (NONE)'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Nov 2020 00:16:44
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	10 Nov 2020 00:16:22
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).		11 Dec 2020 07:53:15
Query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' answered with 'updated dates' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:32:47
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication. However, the ConMed recorded were given prior to the start date of this AE. Please review and reconcile AE and CM start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:17:50
User entered '1' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:44
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered '0'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Gerardo Pena (b) (4)	16 Feb 2021 23:22:05
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 00:16:44
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Nov 2020 00:16:44
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:44
User opened query 'Data is required. Please complete.' (Site from System).	System	10 Nov 2020 00:16:22
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered empty.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:12:41
User entered 'Vertigo was reported as symptom alongside Fibromuscular dysplasia SAE.'	Antonio Gutierrez (b) (4)	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User entered '0'	System	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06
User entered 'I'	System	10 Nov 2020 00:16:22

US3292236

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:28:29

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 13:05:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:25
User closed query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:04:33
Query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' answered with 'botox added' (Site from DM).	Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:37
User opened query 'Per CDM Review: "Have you ever received facial cosmetic injections?" is checked YES on the eDiary, however, there are no Concomitant Procedures, Concomitant Medications, or Medical History capturing that this patient has ever received a cosmetic injection. Please review and update the database as appropriate or confirm if the eDiary response was in error.' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 09:00:24
Query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.	(b) (4), (b) (6)	23 Mar 2021 09:00:18
' canceled (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 05:34:00
User opened query 'Per CDM: Dermal Filler is YES, but no corresponding Con Med or Procedure appears to indicate a dermal filler. Please reconcile or provide clarification.	(b) (4), (b) (6)	
' (Site from DM).	(b) (4), (b) (6)	
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Query 'Per Patient Discharge Summary, Meclizine 25 mg was prescribed to subject. Please confirm/update CM list.' canceled (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 18:19:44

PRODUCTION RELEASE (v12.003
EAB) (1725)

1964 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:28:29

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per Patient Discharge Summary, Meclizine 25 mg was prescribed to subject. Please confirm/update CM list.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:49:08
		21 Oct 2020 18:14:54
User entered 'Yes (Y)'		21 Aug 2020 13:44:48

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:47:22
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 Aug 2020 13:47:22
Data point term sent to Coder	System	21 Aug 2020 13:46:11
User entered 'Calcium'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Osteopenia'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '1800'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.		21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'un UNK 2000'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Yes (Y)'		21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.		21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 13:45:54

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:48:28
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 Aug 2020 13:48:28
Data point term sent to Coder	System	21 Aug 2020 13:47:12
User entered 'Magnesium'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:17:22
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:13:16
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:09
DataPoint Un-verified.	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:01
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:01
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 16:53:43
DataPoint Verified.		21 Oct 2020 18:15:39
User entered 'No (N)'		21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Nutritional supplement'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '500'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.		21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'un UNK 2015'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 13:46:33

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: POTASSIUM, ATC: POTASSIUM, PRODUCT: POTASSIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:49:18
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 Aug 2020 13:49:18
Data point term sent to Coder	System	21 Aug 2020 13:48:14
User entered 'Potassium'	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:17:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:13:20
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:38
DataPoint Un-verified.	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:31
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 16:53:52
DataPoint Verified.		21 Oct 2020 18:15:39
User entered 'No (N)'		21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Nutritional supplement'		21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered '198'		21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'mg (mg)'		21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'un UNK 2015'	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 13:47:25

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: OTHER ALIMENTARY TRACT AND METABOLISM PRODUCTS, ATC: VARIOUS ALIMENTARY TRACT AND METABOLISM PRODUCTS, PRODUCT: UBIDECARENONE, PRODUCTSYNONYM: COENZYME Q10 [UBIDECARENONE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:51:21
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 Aug 2020 13:51:21
Data point term sent to Coder	System	21 Aug 2020 13:50:27
User entered 'Coenzyme Q10'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:17:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:13:25
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:59
DataPoint Un-verified.	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:53
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	06 Jan 2021 22:21:53
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 16:54:01
DataPoint Verified.		21 Oct 2020 18:15:39
User entered 'No (N)'		21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Nutritional supplement'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '100'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'un UNK 2017'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 13:49:31

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: CURCUMA LONGA, PRODUCTSYNONYM: TURMERIC [CURCUMA LONGA] - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:51:21
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 Aug 2020 13:51:21
Data point term sent to Coder	System	21 Aug 2020 13:50:28
User entered 'Turmeric'	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:17:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 14:13:32
Query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	06 Jan 2021 22:22:20
DataPoint Un-verified.	Victoria Hernandez (b) (4)	06 Jan 2021 22:22:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	06 Jan 2021 22:22:14
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given as a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 16:54:09
DataPoint Verified.		21 Oct 2020 18:15:39
User entered 'No (N)'		21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Nutritional supplement'		21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '500'	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'mg (mg)'		21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'un UNK 2015'	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 13:50:24

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: SELECTIVE SEROTONIN (5HT1) AGONISTS, PRODUCT: SUMATRIPTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:53:29
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 Aug 2020 13:53:29
Data point term sent to Coder User entered 'Sumatriptan'	System (b) (4), (b) (6)	21 Aug 2020 13:52:34 21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 18:15:39
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).		06 Oct 2020 14:21:08
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 'Migraine headaches was added to medical history on August 21, 2020.' (Site from DM).	Kevin Martinez (b) (4)	21 Sep 2020 22:22:44
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)	
User entered 'Migraine headaches'	(b) (4), (b) (6)	18 Sep 2020 11:28:12
		21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '100'	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'mg (mg)'		21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'as needed (PRN)'	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'un UNK 1985'	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Yes (Y)'		21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.		21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'No (N)'		21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 13:52:15

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 13:54:15
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 Aug 2020 13:54:15
Data point term sent to Coder User entered 'Fish oil'	System (b) (4), (b) (6)	21 Aug 2020 13:53:36 21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Hyperlipidemia'		21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered '100'		21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'mg (mg)'		21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'once daily (QD)'		21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.		21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Oral (ORAL)'		21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.		21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'un UNK 2015'	(b) (4), (b) (6)	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 18:15:39
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 13:52:47

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: ANTIMIGRAINE PREPARATIONS, ATC: CALCITONIN GENE-RELATED PEPTIDE (CGRP) ANTAGONISTS, PRODUCT: ERENUMAB, PRODUCTSYNONYM: AIMOVIG [ERENUMAB] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 04:56:52
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 04:56:52
Data point term sent to Coder	System	21 Sep 2020 22:37:29
User entered 'Aimovig'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' answered with 'DOES NOT MEET CRITERIA FOR AE' (Site from DM).	(b) (4), (b) (6)	30 Nov 2020 11:38:27
Victoria Hernandez	(b) (4)	05 Nov 2020 19:56:26
Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.'	(b) (4)	
answered with 'DOES NOT MEET CRITERIA FOR AE' (Site from DM).		
User opened query 'Per DM CLR: Please note that there is no AE or Diary event that matches this Con med indication. Review if this should be recorded as an Adverse Event. Else, provide clarification if this will not be recorded on AE ECRF.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 12:22:04
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Migraine Headaches'	Kevin Martinez (b) (4)	21 Sep 2020 22:37:06
	(b) (4)	

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered '70'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'mg (mg)'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'once (ONCE)'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Subcutaneous (SUBCUTANEOUS)'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered empty.	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered '21 Aug 2020'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered '0'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered '21 Aug 2020'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 18:15:39
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User entered empty.	System	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User entered empty.	System	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:43
User entered empty.	System	21 Sep 2020 22:37:06

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:13:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 07:13:25
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	22 Feb 2021 21:15:39
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: OTHER ANTIEMETICS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:18:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:18:38
Data point term sent to Coder Coding entries removed.	System Antonio Gutierrez (b) (4)	10 Nov 2020 00:18:15 10 Nov 2020 00:17:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:21:55
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:09:29
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Nov 2020 06:09:29
Data point term sent to Coder	System	05 Nov 2020 23:21:22

PRODUCTION RELEASE (v12.003
EAB) (1725)

2110 of 2333

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'Meclizine'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:17:45
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User closed query 'Per CDM: Please review and confirm if this pertains to 'FIBROMUSCULAR DYSPLASIA (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	15 Dec 2020 12:34:07
Query 'Per CDM: Please review and confirm if this pertains to 'FIBROMUSCULAR DYSPLASIA (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	24 Nov 2020 22:30:18
User opened query 'Per CDM: Please review and confirm if this pertains to 'FIBROMUSCULAR DYSPLASIA (# 1) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	14 Nov 2020 17:00:24
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	10 Nov 2020 00:17:40
User entered 'Vertigo' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 00:17:40
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered 'Dizziness due to fibromuscular dysplasia'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered '25'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered 'mg (mg)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered 'three times daily (TID)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered 'Oral (ORAL)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
DataPoint Verified.	(b) (4)	19 Apr 2021 19:42:05
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User closed query 'Per DM CLR: Con Med start date is after the stop date of the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 17:53:44
Query 'Per DM CLR: Con Med start date is after the stop date of the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	13 Apr 2021 15:50:02
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	13 Apr 2021 15:49:55
Signature has been broken.	Antonio Gutierrez (b) (4)	13 Apr 2021 15:49:55
User entered '04 Sep 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	13 Apr 2021 15:49:55
User opened query 'Per DM CLR: Con Med start date is after the stop date of the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:01:34
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered '05 Sep 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered '0'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
DataPoint Verified.	(b) (4)	19 Apr 2021 19:41:47
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Un-verified.	(b) (4), (b) (6)	07 Apr 2021 21:18:35
DataPoint Verified.	(b) (4)	07 Apr 2021 21:17:48
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	11 Mar 2021 10:40:28
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	10 Mar 2021 19:21:06
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	10 Mar 2021 19:20:59
Signature has been broken.	Antonio Gutierrez (b) (4)	10 Mar 2021 19:20:59
User entered 'No (N)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	10 Mar 2021 19:20:59
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 04:40:46
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
DataPoint Verified.		19 Apr 2021 19:41:50
User closed query 'End date not present in source.,' (Site from CRA).		19 Apr 2021 19:41:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
Query 'End date not present in source.,' answered with 'updated' (Site from CRA).	(b) (4)	
	Antonio Gutierrez (b) (4)	13 Apr 2021 15:50:06
User opened query 'End date not present in source.,' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 21:18:51
DataPoint Un-verified.		07 Apr 2021 21:18:37
DataPoint Verified.		07 Apr 2021 21:17:50
User entered '05 Sep 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	10 Mar 2021 19:22:02
DataPoint Un-verified.	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Mar 2021 19:20:59
Signature has been broken.	Antonio Gutierrez (b) (4)	10 Mar 2021 19:20:59
User entered '5 Sep 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	10 Mar 2021 19:20:59
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:21:55
User entered 'No (N)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User entered '3'	System	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User entered 'I'	System	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 22:44:44
User entered '804 (804)'	System	05 Nov 2020 23:20:53

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User coded data point as ATC: DERMATOLOGICALS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICAL PREPARATIONS, ATC: OTHER DERMATOLOGICALS, PRODUCT: BOTULINUM TOXIN TYPE A, PRODUCTSYNONYM: BOTOX - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Apr 2021 17:28:27
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 17:28:27
Data point term sent to Coder	System	13 Apr 2021 16:16:49
User entered 'Botox'	Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:48:31
User closed query 'Please update to yes as Botox is considered cosmetic prophylaxis ' (Site from CRA).	(b) (4)	20 Apr 2021 16:23:58
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:23:56
Query 'Please update to yes as Botox is considered cosmetic prophylaxis ' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	20 Apr 2021 15:54:45
Signature has been broken.	(b) (4)	20 Apr 2021 15:54:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Dawn Killian (b) (4)	20 Apr 2021 15:54:41
DataPoint Un-verified.	(b) (4)	19 Apr 2021 19:42:58
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:54
User opened query 'Please update to yes as Botox is considered cosmetic prophylaxis ' (Site from CRA).		19 Apr 2021 19:42:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'No (N)'	(b) (4)	13 Apr 2021 16:16:26
	Antonio Gutierrez (b) (4)	

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'Cosmetic facial injection'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'l'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'Other (OTHER)'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'injection'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'once (ONCE)'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered empty.	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'UN Apr 2020'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'UN Apr 2020'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
DataPoint Verified.		19 Apr 2021 19:42:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
User entered 'No (N)'	(b) (4) Antonio Gutierrez (b) (4)	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
User entered empty.	System	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
User entered empty.	System	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:28:29

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 11:20:05
User entered empty.	System	13 Apr 2021 16:16:26

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:28:29

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:25
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:18:42
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:51:50

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:19:37
User entered '4 Sep 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:53:51

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:19:37
User entered 'Brain MRI'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:53:51

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:59:44
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Un-verified.	(b) (4)	
	Antonio Gutierrez (b) (4)	24 Nov 2020 22:23:14
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:23:14
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:19:37
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:53:51

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:28:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:19:37
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 23:53:51

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:29

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:19:37
User entered '4 Sep 2020'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:54:45

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:29

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:59:48
DataPoint Un-verified.		07 Apr 2021 21:20:27
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:19:37
User entered 'Brain MRA'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:54:45

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:29

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:59:50
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Un-verified.	(b) (4)	
	Antonio Gutierrez (b) (4)	24 Nov 2020 22:23:33
User entered 'Diagnostic (DIAGNOSTIC)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	24 Nov 2020 22:23:33
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 16:19:37
User entered 'Adverse Event (AE)'	Antonio Gutierrez (b) (4)	05 Nov 2020 23:54:45

US3292236

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:28:29

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 16:19:37
User entered empty.	Antonio Gutierrez (b) (4)	05 Nov 2020 23:54:45

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:13:09
User entered '10/Sep/2020 13:31'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'l'		10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: [City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:13:09
User entered '22/Sep/2020 10:49'	System	22 Sep 2020 14:49:37

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
User entered 'l'		22 Sep 2020 14:49:37

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:13:09
User entered '25/Sep/2020 16:49'	System	25 Sep 2020 16:49:05

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
User entered 'l'		25 Sep 2020 16:49:05

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'		10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'		10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:05:15
User entered '14/Oct/2020 13:36'	System	14 Oct 2020 13:36:22

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
User entered 'l'		14 Oct 2020 13:36:22

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:28:29

Date of submission (Pre-filled from custom function)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:44
User entered '05/Nov/2020 15:03'	System	05 Nov 2020 15:03:21

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	23 Nov 2020 15:15:46
Reviewed for Safety.	(b) (4), (b) (6)	06 Nov 2020 14:30:53
User entered 'l'		05 Nov 2020 15:03:21

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'		10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:15:34
User entered '06/Nov/2020 14:31'	System	06 Nov 2020 14:31:10

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	25 Nov 2020 18:06:12
DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 15:15:36
User entered 'l'		06 Nov 2020 14:31:10

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:06:50
DataPoint Un-verified.		21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'		14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.		19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:16:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '25/Nov/2020 13:06'	(b) (4) System	25 Nov 2020 18:06:23

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:16:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	17 Feb 2021 16:24:56
User entered 'l'		25 Nov 2020 18:06:23

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:16:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered '17/Feb/2021 16:25'	(b) (4) System	17 Feb 2021 16:25:12

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	07 Apr 2021 21:16:10
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
User entered 'I'	(b) (4), (b) (6)	17 Feb 2021 16:25:12

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:46
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:19
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'USA-US072-2020-MRNA-1273-P301000001'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Serious

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:48
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:22
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Death

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:50
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:21
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:52
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:25
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	21 Oct 2020 19:06:53
DataPoint Un-verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:27
DataPoint Verified.		01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'Yes (Y)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 17:31:25
User entered 'No (N)'	System	10 Sep 2020 17:22:57

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Douglas'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'Denham'		14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered '7940 Floyd Curl Drive'	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered '5430 Fredericksburg Rd, Ste. 200'	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
reason for change: Data Entry Error		
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '7940 Floyd Curl Drive'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered 'San Antonio'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Nov 2020 15:03:09
DataPoint Verified.		21 Oct 2020 19:05:15
Un-reviewed for Safety.	System	14 Oct 2020 13:36:22
DataPoint Un-verified.	System	14 Oct 2020 13:36:22
User entered empty.	System	14 Oct 2020 13:36:22
Reviewed for Safety.	(b) (4), (b) (6)	14 Oct 2020 13:36:10
DataPoint Verified.		01 Oct 2020 19:13:09
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	26 Sep 2020 17:38:03
Reviewed for Safety.	(b) (4), (b) (6)	25 Sep 2020 16:48:54
Un-reviewed for Safety.	System	22 Sep 2020 14:49:37
User entered empty.	System	22 Sep 2020 14:49:37
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
User entered 'Texas'	Kevin Martinez (b) (4)	21 Sep 2020 22:30:54
	(b) (4)	

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	01 Oct 2020 19:13:09
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 14:49:27
Amendment Manager: User entered '78229'	System	14 Sep 2020 22:04:16

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:13:09
Reviewed for Safety.		22 Sep 2020 14:49:27
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 01:42:07
User entered 'US' (non-conformant).	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 16:28:29

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '9'	System	11 Mar 2021 16:30:30
User signature succeeded.	Douglas Denham (b) (4)	22 Feb 2021 21:15:39
	(b) (4)	
User entered '8'	System	17 Feb 2021 16:25:12
User entered '7'	System	25 Nov 2020 18:06:23
User entered '6'	System	06 Nov 2020 14:31:10
User entered '5'	System	05 Nov 2020 15:03:21
User entered '4'	System	14 Oct 2020 13:36:22
User entered '3'	System	25 Sep 2020 16:49:05
User entered '2'	System	22 Sep 2020 14:49:37
User entered '1'	System	10 Sep 2020 17:31:34

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:28:29

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Apr 2021 21:16:10
User entered '11/Mar/2021 11:30'	System	11 Mar 2021 16:30:30

US3292236

Folder: SAE USA-US072-2020-MRNA-1273-P301000001

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 16:28:29

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:18:49
DataPoint Verified.	(b) (4)	07 Apr 2021 21:16:10
User entered 'I'	(b) (4), (b) (6)	11 Mar 2021 16:30:30