

US3292304 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:30:09

All time stamps listed in this document are displayed in GMT

US3292304

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

---

[Participant ID](#)

US3292304

---

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

---

---

US3292304

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3292304

Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Date of Birth (MMM yyyy)	(b) (6) 1985
Age	35
Age Units	YEARS
Age (Derived)	35
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False



US3292304

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Date of Informed Consent ( <i>dd MMM yyyy</i> )	25 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 type="radio"/> Amendment 3 <input checked="" 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

US3292304

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

---

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

---

US3292304

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

---

Were any significant conditions reported?

Yes ☒  
No ☐

---

US3292304

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	ENVIRONMENTAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292304

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	PECAN ALLERGY
Start date (dd MMM yyyy)	UN UNK 1992
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 1992
Start Year (derived)	1992
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292304

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	CLEFT LIP REPAIR
Start date (dd MMM yyyy)	UN (b) (6) 1985
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 (b) (6) 1985
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1985
Start Year (derived)	1985
Stop Month and Year (derived)	(b) (6) 1985
Stop Year (derived)	1985

US3292304

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	ORTHOSCOPIC MENISCUS REPAIR
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003

US3292304

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	COLONOSCOPY
Start date (dd MMM yyyy)	UN APR 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 APR 2019
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	APR 2019
Stop Year (derived)	2019



US3292304

Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	SMALL POLYP REMOVAL IN COLON
Start date (dd MMM yyyy)	UN APR 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 APR 2019
Stop date completely unknown	False
Start Month and Year (derived)	APR 2019
Start Year (derived)	2019
Stop Month and Year (derived)	APR 2019
Stop Year (derived)	2019

US3292304

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	ENDOSCOPY
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3292304

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	STEROID INJECTION DUE TO INFLAMMED DISKS IN BACK DUE TO MOTORCYCLE ACCIDENT
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3292304

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	WISDOM TEETH REMOVAL
Start date (dd MMM yyyy)	UN UNK 2004
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 2004
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2004
Start Year (derived)	2004
Stop Month and Year (derived)	JAN 2004
Stop Year (derived)	2004

US3292304

Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	CLEFT LIP
Start date (dd MMM yyyy)	(b) (6) 1985
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)	(b) (6) 1985
Stop date completely unknown	False
Start Month and Year (derived)	(b) (6) 1985
Start Year (derived)	1985
Stop Month and Year (derived)	(b) (6) 1985
Stop Year (derived)	1985

US3292304

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	L4-L5 BULGING DISCS
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

US3292304

Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	TORN MENISCUS RIGHT KNEE
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2003
Start Year (derived)	2003
Stop Month and Year (derived)	JAN 2003
Stop Year (derived)	2003



US3292304

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN JAN 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292304

Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	ADULT FACIAL ACNE
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)	_____

US3292304

Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 22 Apr 2021 15:51:06

Generated On: 09 Jun 2021 16:30:09

Condition	STOMACH PAIN
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2007
Start Year (derived)	2007
Stop Month and Year (derived)	JAN 2007
Stop Year (derived)	2007

US3292304

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	25 AUG 2020
Time of assessment (00:00-23:59)	11:13 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 11:13
Height (xxx.x)	173.9 cm
Weight (xxx.x)	79.2 kg
BMI (xxx.x)	26.18943 kg/m <sup>2</sup>
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	ND - Not Done
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292304

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

25 AUG 2020

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

US3292304

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

---

**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

US3292304

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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



US3292304

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

What was the date of randomization? (dd MMM yyyy) 25 AUG 2020

What was the participant's randomization number? 108329

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 ☒

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Height	ND - Not Done
Weight	ND - Not Done

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

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)	25 AUG 2020
Time of assessment (00:00-23:59)	12:05 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 12:05
Temperature (xxx.x)	036.1 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	075 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	015 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	131 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	089 mmHg
Diastolic Blood Pressure units	MMHG

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

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)	25 AUG 2020
Time of assessment (00:00-23:59)	14:21 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 14:21
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	80 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG

US3292304

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

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.*

US3292304

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

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) 25 AUG 2020

What was the treatment time? (00:00-23:59) 13:42 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 13:42

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

US3292304

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 AUG 2020
Collection time (00:00-23:59)	12:11 (24 HR)
Collection date and time (derived)	25 AUG 2020 12:11

US3292304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Collection date (dd MMM yyyy)			25 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:32	25 AUG 2020 12:32
Nasopharyngeal Swab 2	No		



US3292304

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**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

97.7 °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

25 AUG 2020 14:27

PC Open Date & Time

25 AUG 2020 14:02

PC Close Date & Time

25 AUG 2020 16:32

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒  
No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐  
No ☒

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

PC Time Stamp	25 AUG 2020 22:30
PC Open Date & Time	25 AUG 2020 17:27
PC Close Date & Time	26 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 22:24

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °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

27 AUG 2020 22:31

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**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

28 AUG 2020 22:28

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 19:46

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 21:32

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

---

**TIMEPOINT**

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 23:42

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**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

25 AUG 2020 14:27

PC Open Date & Time

25 AUG 2020 14:02

PC Close Date & Time

25 AUG 2020 16:32

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**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

25 AUG 2020 22:32

PC Open Date & Time

25 AUG 2020 17:27

PC Close Date & Time

26 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**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

26 AUG 2020 22:26

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**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

27 AUG 2020 22:32

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**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

28 AUG 2020 22:28

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**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

29 AUG 2020 19:46

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**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

30 AUG 2020 21:32

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59



US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**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

31 AUG 2020 23:43

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**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 ☐

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 14:28
PC Open Date & Time	25 AUG 2020 14:02
PC Close Date & Time	25 AUG 2020 16:32

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**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 ☐

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 22:33
PC Open Date & Time	25 AUG 2020 17:27
PC Close Date & Time	26 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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

57 of 2331

EAB) (1725)

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 22:26
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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 2331

EAB) (1725)



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 22:32
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**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 2331

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 22:29
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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 2331

EAB) (1725)

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:47
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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 2331

EAB) (1725)

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 21:33
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

67 of 2331

EAB) (1725)



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 23:43
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3292304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

09 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	22 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



US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

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)	22 SEP 2020
Time of assessment (00:00-23:59)	10:49 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 10:49
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)	78 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

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)	22 SEP 2020
Time of assessment (00:00-23:59)	12:22 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 12:22
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	63 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	114 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3292304

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

22 SEP 2020

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

US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

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) 22 SEP 2020

What was the treatment time? (00:00-23:59) 11:51 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 11:51

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

US3292304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

11:01 (24 HR)

Collection date and time (derived)

22 SEP 2020 11:01

US3292304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Collection date (dd MMM yyyy)			22 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	11:04	22 SEP 2020 11:04
Nasopharyngeal Swab 2	No		

US3292304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**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

22 SEP 2020 12:24

PC Open Date & Time

22 SEP 2020 12:11

PC Close Date & Time

22 SEP 2020 14:41



US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 1, AFTER VACCINATION  
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.8 °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	22 SEP 2020 23:28
PC Open Date & Time	22 SEP 2020 15:36
PC Close Date & Time	23 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**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 <b>TEMPERATURE</b> taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your <b>TEMPERATURE</b> in °F	100.8 °F
Was any <b>MEDICATION TAKEN</b> today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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

To <b>TREAT</b> pain or fever that has already occurred	True
To <b>PREVENT</b> pain or fever from occurring	False

PC Time Stamp	23 SEP 2020 15:12
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 23:05

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 23:00

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 26 SEP 2020 19:29

PC Open Date & Time 26 SEP 2020 12:00

PC Close Date & Time 27 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**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

97.7 °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

27 SEP 2020 23:59

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**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 ☒

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

Yes ☐

No ☒

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

PC Time Stamp 29 SEP 2020 10:39

PC Open Date & Time 28 SEP 2020 12:00

PC Close Date & Time 29 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**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

22 SEP 2020 12:24

PC Open Date & Time

22 SEP 2020 12:11

PC Close Date & Time

22 SEP 2020 14:41



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**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 ☐

Please record - **REDNESS AT INJECTION SITE (in mm)**

2

Measure the largest size across any injection site redness with the  
ruler provided.

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

22 SEP 2020 23:30

PC Open Date & Time

22 SEP 2020 15:36

PC Close Date & Time

23 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**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

23 SEP 2020 15:12

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**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

24 SEP 2020 23:06

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**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

25 SEP 2020 23:01

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**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

26 SEP 2020 19:29

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**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

28 SEP 2020 00:00

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

PC Time Stamp

29 SEP 2020 10:39

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**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 ☐



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 12:24
PC Open Date & Time	22 SEP 2020 12:11
PC Close Date & Time	22 SEP 2020 14:41

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**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 ☐

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 23:31
PC Open Date & Time	22 SEP 2020 15:36
PC Close Date & Time	23 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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

103 of 2331

EAB) (1725)

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 15:13
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003  
EAB) (1725)

105 of 2331

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	24 SEP 2020 23:06
PC Open Date & Time	24 SEP 2020 12:00
PC Close Date & Time	25 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**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 2331



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 23:01
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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 2331

EAB) (1725)

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 19:30
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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

111 of 2331

EAB) (1725)

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain  
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily  
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires  
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity  
not requiring medical attention ☐

Prevents daily activity and  
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

113 of 2331

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

Yes <input type="checkbox"/>	
PC Time stamp	29 SEP 2020 10:40
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3292304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 OCT 2020

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

Comments  
*If Contact Not Made, please provide Comments*  
ATTEMPTED TO CONTACT  
PATIENT 3X NO ANSWER,  
UNABLE TO LVM DUE TO  
MAILBOX NOT BEING SET UP.



US3292304

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

7 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted? Yes ☒  
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 OCT 2020

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

Comments CONTACTED SUBJECT 3X W/  
SMS SENT.

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	30 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

US3292304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	30 OCT 2020
Time of assessment (00:00-23:59)	12:44 (24 HR)
Vital Signs Date and Time (derived)	30 OCT 2020 12:44
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)	96 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

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.*



US3292304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	30 OCT 2020
Collection time (00:00-23:59)	12:57 (24 HR)
Collection date and time (derived)	30 OCT 2020 12:57

US3292304

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:28

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq$ 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this 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 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 71
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	01 NOV 2020 08:38:58
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	08 NOV 2020 10:51:46
Patient Cloud Open Date & Time	08 NOV 2020 00:01
Patient Cloud Close Date & Time	12 NOV 2020 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 89
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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

---

[Patient Cloud Close Date & Time](#)

---

23 NOV 2020 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2020 00:01

---

[Patient Cloud Close Date & Time](#)

---

30 NOV 2020 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

03 DEC 2020 21:43:33

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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	10 DEC 2020 01:17:55
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

17 DEC 2020 00:25:44

Patient Cloud Open Date & Time

17 DEC 2020 00:01

Patient Cloud Close Date & Time

21 DEC 2020 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	27 DEC 2020 12:48:32
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

<b>TIMEPOINT</b>	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	31 DEC 2020 00:03:12
Patient Cloud Open Date & Time	31 DEC 2020 00:01
Patient Cloud Close Date & Time	04 JAN 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

07 JAN 2021 00:02:49

Patient Cloud Open Date & Time

07 JAN 2021 00:01

Patient Cloud Close Date & Time

11 JAN 2021 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

<b>TIMEPOINT</b>	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	14 JAN 2021 00:06:59
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 152
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	21 JAN 2021 00:45:06
Patient Cloud Open Date & Time	21 JAN 2021 00:01
Patient Cloud Close Date & Time	25 JAN 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

28 JAN 2021 00:12:21

Patient Cloud Open Date & Time

28 JAN 2021 00:01

Patient Cloud Close Date & Time

01 FEB 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

<b>TIMEPOINT</b>	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	04 FEB 2021 00:01:47
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

11 FEB 2021 09:29:32

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 FEB 2021 00:03:48

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	25 FEB 2021 00:02:02
Patient Cloud Open Date & Time	25 FEB 2021 00:01
Patient Cloud Close Date & Time	01 MAR 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

<b>TIMEPOINT</b>	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 MAR 2021 00:23:25
Patient Cloud Open Date & Time	04 MAR 2021 00:01
Patient Cloud Close Date & Time	08 MAR 2021 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	11 MAR 2021 00:01:26
Patient Cloud Open Date & Time	11 MAR 2021 00:01
Patient Cloud Close Date & Time	15 MAR 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

18 MAR 2021 00:01:25

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

25 MAR 2021 00:02:01

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

01 APR 2021 00:01:44

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

08 APR 2021 00:01:50

Patient Cloud Open Date & Time

08 APR 2021 00:01

Patient Cloud Close Date & Time

12 APR 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	15 APR 2021 00:19:25
Patient Cloud Open Date & Time	15 APR 2021 00:01
Patient Cloud Close Date & Time	19 APR 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

25 APR 2021 20:09:06

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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

29 APR 2021 00:01:21

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

10 MAY 2021 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

17 MAY 2021 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

20 MAY 2021 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 MAY 2021 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

31 MAY 2021 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

07 JUN 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

21 JUN 2021 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 JUN 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 JUN 2021 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	08 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	12 JUL 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	15 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	19 JUL 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

26 JUL 2021 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	29 JUL 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	02 AUG 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	12 AUG 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	16 AUG 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

23 AUG 2021 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 <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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 376
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	09 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	13 SEP 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 SEP 2021 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 SEP 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 SEP 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

04 OCT 2021 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	07 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	11 OCT 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 425
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 OCT 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	28 OCT 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	01 NOV 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	11 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	15 NOV 2021 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	18 NOV 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	22 NOV 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

29 NOV 2021 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	02 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	06 DEC 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 DEC 2021 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 DEC 2021 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	03 JAN 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

10 JAN 2022 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

17 JAN 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

20 JAN 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

24 JAN 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

31 JAN 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

14 FEB 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	17 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	21 FEB 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 <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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	24 FEB 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	28 FEB 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

07 MAR 2022 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	10 MAR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	14 MAR 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

21 MAR 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

24 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

28 MAR 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

31 MAR 2022 00:01

---

[Patient Cloud Close Date & Time](#)

---

04 APR 2022 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 <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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

11 APR 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 APR 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 APR 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

25 APR 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

02 MAY 2022 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

09 MAY 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

16 MAY 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 <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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 <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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	16 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	20 JUN 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	23 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	27 JUN 2022 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	30 JUN 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	04 JUL 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	14 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	18 JUL 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	21 JUL 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	25 JUL 2022 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

01 AUG 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	04 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	08 AUG 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

15 AUG 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

22 AUG 2022 23:59

---



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	25 AUG 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	29 AUG 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT	DAY 754
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$ )	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

19 SEP 2022 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	22 SEP 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	26 SEP 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**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 ☐

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

10 OCT 2022 23:59

---

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	13 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	17 OCT 2022 23:59



US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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 <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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	
<a href="#">Patient Cloud Open Date &amp; Time</a>	20 OCT 2022 00:01
<a href="#">Patient Cloud Close Date &amp; Time</a>	24 OCT 2022 23:59

US3292304

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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"/>

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

---

[Patient Cloud Close Date & Time](#)

---

31 OCT 2022 23:59

---

**US3292304**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary**

**Generated On: 09 Jun 2021 16:30:09**

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		28 FEB 2021 12:09:22

US3292304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

17 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:27

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*



US3292304

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 FEB 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:36:14

Generated On: 09 Jun 2021 16:30:09

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

Visit date (dd MMM yyyy)	22 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
------------	--------

US3292304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:36:14

Generated On: 09 Jun 2021 16:30:09

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) \_\_\_\_\_

US3292304

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:36:14

Generated On: 09 Jun 2021 16:30:09

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.*



US3292304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:36:14

Generated On: 09 Jun 2021 16:30:09

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 MAR 2021

Collection time (00:00-23:59)

12:54 (24 HR)

Collection date and time (derived)

22 MAR 2021 12:54

US3292304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:36:14

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292304

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:38:20

Generated On: 09 Jun 2021 16:30:09

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

*If Contact Not Made, please provide Comments*

US3292304

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:38:20

Generated On: 09 Jun 2021 16:30:09

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

**US3292304**

**Folder: Safety Call Day 269 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

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*

**US3292304**

**Folder: Safety Call Day 269 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

**US3292304**

**Folder: Covid-19 Assessment (1)**

**Form: COVID-19 Contact**

**Generated On: 09 Jun 2021 16:30:09**

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"/>

**US3292304**

**Folder: Covid-19 Assessment (1)**

**Form: Generate Next COVID-19 Assessment**

**Generated On: 09 Jun 2021 16:30:09**

---

Generate Next COVID-19 Assessment

Yes ☐

No ☐

---



US3292304

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 17:08:09

Generated On: 09 Jun 2021 16:30:09

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

Visit date (dd MMM yyyy)	2 MAR 2021
--------------------------	------------

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

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

US3292304

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 18:34:24

Generated On: 09 Jun 2021 16:30:09

Date of updated informed consent (dd MMM yyyy) 2 MAR 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 2 MAR 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag \_\_\_\_\_  
Continuing with mRNA-1273 \_\_\_\_\_

US3292304

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 17:08:09

Generated On: 09 Jun 2021 16:30:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00-23:59)	11:22 (24 HR)
Collection date and time (derived)	2 MAR 2021 11:22

US3292304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 17:08:09

Generated On: 09 Jun 2021 16:30:09

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00 - 23:59)	11:31
Collection Date and Time (derived)	2 MAR 2021 11:31

US3292304

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

---

Did the participant experience any adverse events?

Yes ☒

No ☐

---

If Yes, enter details on the Adverse Events form.

---

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

AEID	USA-US072-2020-MRNA-1273-P30 1000005
Adverse event	PERFORATED COLON
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 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	6 OCT 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	04 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	16 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

337 of 2331

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

---

SUBJECT WAS CALLED FOR  
DAY 43 SAFETY CALL, HE THEN  
STATED HE WAS IN THE  
HOSPITAL DUE TO HAVING  
EMERGENCY SURGERY FOR A  
PERFORATED COLON , HE  
STATED SYMPTOMS STARTED  
WHEN HE WOKE UP ON  
SUNDAY (10/4/20) ABOUT 9:00  
AM , HE WAS ADMITTED TO  
THE HOSPITAL ON 10/4/20 AND  
WENT IN FOR SURGERY ON  
10/6/20 AT 19:00 . HOSPITAL  
RECORDS WILL BE REQUESTED  
AND MEDICATIONS AND ALL  
OTHER INFORMATION WILL BE  
UPDATED AS SOON AS  
RECORDS ARE  
RECEIVED.UPDATED  
NARRATIVE AND CONPROC

---

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

---



US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

AEID	USA-US072-2020-MRNA-1273-P30 1000005
Adverse event	PULMONARY EMBOLISM
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	7 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	4 OCT 2020
Hospital Discharge Date (dd MMM yyyy)	16 OCT 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

PRODUCTION RELEASE (v12.003  
EAB) (1725)

340 of 2331

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

---

A PERFORATED COLON WAS A PREVIOUSLY DOCUMENTED FOR THIS PATIENT. THIS PATIENT CAME IN TO CLINIC FOR HIS VISIT 3 ON 30OCT2020. WHILE IN CLINIC, THE PATIENT INFORMED STAFF THAT HE WAS DIAGNOSED WITH A PULMONARY EMBOLISM AFTER HIS SURGERY. PATIENT STATES THAT HE WAS STARTED ON BLOOD THINNERS (XARELTO). PATIENT STATES THAT THIS PE PROLONGED HIS HOSPITALIZATION, THEREFORE THIS SAE IS BEING SUBMITTED. MEDICAL RECORDS FOR BOTH THE PERFORATED COLON AND THE PULMONARY EMBOLISM HAVE BEEN REQUESTED AS OF 30OCT2020.

---

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

---

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

AEID	USA-US072-2021-MRNA-1273-P30 1000010
Adverse event	RIGHT LUNG PULMONARY EMBOLI
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)	15 JAN 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	1 APR 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	15 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	23 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
PRODUCTION RELEASE (v12.003 EAB) (1725)	343 of 2331

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

---

PATIENT HAS BEEN FOLLOWED  
REGULARLY BY HIS  
PULMONOLOGIST DUE TO  
PULMONARY EMBOLISM  
REPORTED EARLIER IN L LUNG.  
FOLLOWING VISIT ON  
15JAN2021, DOCTOR ORDERED  
A STAT CT SCAN FOLLOWING  
PT REPORT OF SMALL  
AMOUNTS OF BLOOD IN HIS  
SPIT IN THE MORNINGS. SCAN  
SHOWED ORIGINAL EMBOLISM  
IN L LUNG STILL PRESENT  
ALONG WITH TWO NEW  
EMBOLI IN R LUNG. PATIENT  
WAS ADMITTED AND HAS  
BEEN HOSPITALIZED SINCE  
WITH ESTIMATED DISCHARGE  
DATE OF 21JAN2021. MEDICAL  
RECORDS WILL BE  
REQUESTED.

---

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

---

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 16 Apr 2021 14:36:14

Generated On: 09 Jun 2021 16:30:09

---

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

Yes ☒

No ☐

---

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

---

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication ZYRTEC

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

347 of 2331



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	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)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication CITRUCEL

Prophylaxis Yes ☒  
No ☐

Indication 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)

349 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	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 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)	4 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication PROBIOTIC

Prophylaxis Yes ☒  
No ☐

Indication DIGESTION SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

351 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication MEGA MAN SPORT  
MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify PK

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

353 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication MEGA MAN PERF  
MULTIVITAMIN

Prophylaxis Yes ☒  
No ☐

Indication HEALTH SUPPLEMENT

Dose per administration 1

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

If dose unit is Other, specify PK

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

355 of 2331



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication TYLENOL

Prophylaxis Yes ☒  
No ☐

Indication PAIN PREVENTATIVE

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)

357 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication TUMERIC

Prophylaxis Yes ☒  
No ☐

Indication HEALTH 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)

359 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	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 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	4 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication GINGER

Prophylaxis Yes ☒  
No ☐

Indication HEALTH SUPPLEMENT

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

361 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	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 MAY 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	4 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication SINGULAIR

Prophylaxis Yes ☐  
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

363 of 2331



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	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 2010	
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"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication DICYCLOMINE

Prophylaxis Yes ☐  
No ☒

Indication DIVERTICULOSIS

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

365 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	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 JUL 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	4 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication XARELTO

Prophylaxis Yes ☐  
No ☒

Indication PROPHYLAXIS

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

367 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	22 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	15 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication WARFARIN

Prophylaxis Yes ☐  
No ☒

Indication PROPHYLAXIS

Dose per administration 7.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

QD (MON TO FRI)

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

369 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication PROTONIX

Prophylaxis Yes ☒  
No ☐

Indication HEALTH SUPPLEMENT

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003  
EAB) (1725)

371 of 2331



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

Name of Medication TYLENOL

Prophylaxis Yes ☐  
No ☒

Indication HEADACHE  
(REACTOGENICITY)

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒  
Topical ☐  
Subcutaneous ☐  
Transdermal ☐

PRODUCTION RELEASE (v12.003  
EAB) (1725)

373 of 2331

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		23 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)		23 SEP 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"/>

US3292304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

---

Were any concomitant procedures performed?

Yes ☒

No ☐

---

If yes, please complete Concomitant Procedures form.

---

US3292304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 23 Feb 2021 14:08:26

Generated On: 09 Jun 2021 16:30:09

Procedure/Surgery date ( <i>dd MMM</i> <i>yyyy</i> )	Procedure/Surgery	Indication	If indication is Other, specify
6 OCT 2020	ILEOSTOMY	Adverse Event	

US3292304

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:30:09

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

US3292304

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:30:09

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 ☐

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2020-MRNA-1273-P301000005
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)	6



US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	08/OCT/2020 08:03
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

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	29/OCT/2020 16:30
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

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	02/NOV/2020 15:57
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	25/NOV/2020 15:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	19/APR/2021 14:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 03 May 2021 14:18:44

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2020-MRNA-1273-P301000005
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)	6
Date of submission (Pre-filled from custom function)	30/APR/2021 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

US3292304

Folder: SAE USA-US072-2021-MRNA-1273-P301000010

Form: Safety Report Form

Data signed: (b) (4) 22 Apr 2021 15:51:05

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2021-MRNA-1273-P301000010
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)	3

US3292304

Folder: SAE USA-US072-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Data signed: (b) (4) 22 Apr 2021 15:51:05

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2021-MRNA-1273-P301000010
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)	3
Date of submission (Pre-filled from custom function)	21/JAN/2021 12:41
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True



US3292304

Folder: SAE USA-US072-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Data signed: (b) (4) 22 Apr 2021 15:51:05

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2021-MRNA-1273-P301000010
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)	3
Date of submission (Pre-filled from custom function)	19/APR/2021 14:34
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

US3292304

Folder: SAE USA-US072-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Data signed: (b) (4) 22 Apr 2021 15:51:05

Generated On: 09 Jun 2021 16:30:09

SAEID	USA-US072-2021-MRNA-1273-P301000010
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)	3
Date of submission (Pre-filled from custom function)	22/APR/2021 10:32
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292304 (Prod: Clinical Trials of Texas, Inc)

**US3292304**

**Form: Participant Creation**

**Generated On: 09 Jun 2021 16:30:09**

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 19:00:47
User entered 'US3292304'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:45:06

**US3292304**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:16:22
User entered 'Yes (Y)'		27 Aug 2020 12:46:44

**US3292304**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:17:12
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:45:07

**US3292304**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:17:14
User entered 'Clinic (Clinic)'		27 Aug 2020 12:46:44

**US3292304**

**Folder: Screening**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'SCRN'	System	27 Aug 2020 12:46:44



US3292304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:09

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:19:12
User entered (b) (6) 1985'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:45:08

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:19:14
User entered '35'		27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'YEARS'	System	27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '35'	System	25 Aug 2020 19:26:08

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:19:16
User entered 'Male (M)'		27 Aug 2020 12:46:58

US3292304

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:30:09

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:19:27
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'	(b) (4), (b) (6)	27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:19:28
User entered 'l'		27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:19:50
User entered '0'		27 Aug 2020 12:46:58



**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:19:50
User entered '0'		27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:19:50
User entered '0'		27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:19:50
User entered '0'		27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:19:50
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:19:50
User entered empty.		27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:19:50
User entered '0'	(b) (4), (b) (6)	7 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Demographics**

**Generated On: 09 Jun 2021 16:30:09**

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:19:50
User entered '0'		27 Aug 2020 12:46:58

**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

**Date of Informed Consent** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:25:54
User entered '25 Aug 2020'		25 Aug 2020 19:26:08



**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Aug 2020'	System	25 Aug 2020 19:26:08

**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2020'	System	25 Aug 2020 19:26:08

**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:25:55
User entered 'Amendment 3 (3)'	(b) (4), (b) (6)	25 Aug 2020 19:26:08

**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:25:58
User entered 'Yes (Y)'		25 Aug 2020 19:26:08

**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:26:07
User entered empty.		25 Aug 2020 19:26:08

**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

[If reason for screen fail is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:26:07
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 19:26:08

**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:26:07
User entered 'No (N)'		25 Aug 2020 19:26:08

**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:26:07
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 16:45:07



**US3292304**

**Folder: Screening**

**Form: Enrollment**

**Generated On: 09 Jun 2021 16:30:09**

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'l'	System	25 Aug 2020 19:26:11

**US3292304**

**Folder: Screening**

**Form: Inclusion/Exclusion Criteria Summary**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 20:59:39
User entered 'Yes (Y)'		25 Aug 2020 19:26:11

US3292304

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:30:09

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 21:00:08
User entered 'Yes (Y)'		27 Aug 2020 12:47:04

US3292304

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.	(b) (4)	09 Mar 2021 16:22:27
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 21:13:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	13 Nov 2020 21:13:44
Data point term sent to Coder	System	13 Nov 2020 21:13:00
DataPoint Un-verified.	Dawn Killian (b) (4)	13 Nov 2020 21:12:56
Coding entries removed.	(b) (4)	
	Dawn Killian (b) (4)	13 Nov 2020 21:12:56
User entered 'ENVIRONMENTAL Allergies' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Dawn Killian (b) (4)	13 Nov 2020 21:12:56
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:46:50
	(b) (4)	
DataPoint Verified.	(b) (4)	01 Oct 2020 16:35:42
	(b) (4)	
DataPoint Verified.	(b) (4)	01 Oct 2020 16:35:01
	(b) (4)	
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Mycotic allergy, LLT: Allergy to molds - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 07:18:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	04 Sep 2020 07:18:40
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Hypersensitivity, LLT: Environmental allergy - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:46
Data point term sent to Coder	System	27 Aug 2020 12:48:05
User entered 'environmental mold allergy'	(b) (4), (b) (6)	27 Aug 2020 12:47:39

US3292304

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:46:51
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un UNK 1992'	(b) (4), (b) (6)	27 Aug 2020 12:47:39

US3292304

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:46:52
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:47:39

**US3292304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:46:54
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 12:47:39

**US3292304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:46:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 12:47:39



US3292304

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:46:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:47:39

**US3292304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 1992'	System	27 Aug 2020 12:47:39

**US3292304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '1992'	System	27 Aug 2020 12:47:39

**US3292304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:47:39

**US3292304**

**Folder: Screening**

**Form: Medical History (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:47:39

US3292304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:32:42
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
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: Allergy to nuts - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 12:23:44
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	11 Sep 2020 12:23:44
Data point term sent to Coder	System	27 Aug 2020 12:49:07
User entered 'pecan allergy'	(b) (4), (b) (6)	27 Aug 2020 12:48:35

US3292304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:04
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un UNK 1992'	(b) (4), (b) (6)	27 Aug 2020 12:48:35

US3292304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:05
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:48:35



US3292304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:07
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 12:48:35

US3292304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:08
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 12:48:35

US3292304

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:33:10
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'		27 Aug 2020 12:48:35

**US3292304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 1992'	System	27 Aug 2020 12:48:35

**US3292304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '1992'	System	27 Aug 2020 12:48:35

**US3292304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:48:35

**US3292304**

**Folder: Screening**

**Form: Medical History (4)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:48:35

US3292304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:42:40
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Lip therapeutic procedures, PT: Cleft lip repair, LLT: Cleft lip repair - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:49
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:49
Data point term sent to Coder	System	27 Aug 2020 12:49:07
User entered 'cleft lip repair'	(b) (4), (b) (6)	27 Aug 2020 12:48:58



US3292304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User closed query 'Per source, Date is UN UNK 1985. Please review and reconcile. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:57:24
	(b) (4), (b) (6)	16 Apr 2021 17:57:22
Query 'Per source, Date is UN UNK 1985. Please review and reconcile. ' answered with 'updating source' (Site from CRA).	Victoria Hernandez (b) (4)	12 Mar 2021 20:02:22
	(b) (4)	
User opened query 'Per source, Date is UN UNK 1985. Please review and reconcile. ' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 16:24:42
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
	(b) (4), (b) (6)	
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	22 Sep 2020 20:56:31
User entered 'UN <sup>(b) (6)</sup> 1985' reason for change: Data Entry Error	Dawn Killian (b) (4)	22 Sep 2020 20:56:31
	(b) (4)	
Comment added 'year of birth'.	(b) (4), (b) (6)	27 Aug 2020 12:49:23
	(b) (4), (b) (6)	
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	System	27 Aug 2020 12:48:58
User entered 'un UNK 1985'	(b) (4), (b) (6)	27 Aug 2020 12:48:58
	(b) (4), (b) (6)	

US3292304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:42:42
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'		27 Aug 2020 12:48:58

US3292304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:42:44
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:48:58

US3292304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User closed query 'Per source, Date is UN UNK 1985. Please review and reconcile.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:57:48
	(b) (4), (b) (6)	16 Apr 2021 17:57:46
Query 'Per source, Date is UN UNK 1985. Please review and reconcile.' answered with 'updating source' (Site from CRA).	Victoria Hernandez (b) (4)	12 Mar 2021 20:02:30
	(b) (4)	
User opened query 'Per source, Date is UN UNK 1985. Please review and reconcile.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 16:24:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
	(b) (4), (b) (6)	
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	22 Sep 2020 20:56:38
User entered 'UN (b) (6) 1985' reason for change: Data Entry Error	Dawn Killian (b) (4)	22 Sep 2020 20:56:38
	(b) (4)	
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	System	22 Sep 2020 20:56:31
User entered 'un UNK 1985'	(b) (4), (b) (6)	27 Aug 2020 12:48:58
	(b) (4), (b) (6)	

US3292304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:42:47
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:48:58

**US3292304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered (b) (6) 1985'	System	22 Sep 2020 20:56:31
User entered 'Jan 1985'	System	27 Aug 2020 12:48:58

**US3292304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '1985'	System	27 Aug 2020 12:48:58

US3292304

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered (b) (6) 1985'	System	22 Sep 2020 20:56:38
User entered 'Jan 1985'	System	27 Aug 2020 12:48:58



**US3292304**

**Folder: Screening**

**Form: Medical History (5)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '1985'	System	27 Aug 2020 12:48:58

US3292304

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Meniscus operation, LLT: Meniscus operation - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 00:52:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 00:52:01
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:28:32
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
Data point term sent to Coder	System	27 Aug 2020 12:50:10
User entered 'orthoscopic meniscus repair'	(b) (4), (b) (6)	27 Aug 2020 12:50:08

US3292304

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:34
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un UNK 2003'	(b) (4), (b) (6)	27 Aug 2020 12:50:08

US3292304

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:35
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:50:08

US3292304

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:37
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:50:08

**US3292304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:39
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un UNK 2003'	(b) (4), (b) (6)	27 Aug 2020 12:50:08

US3292304

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:40
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:50:08

**US3292304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2003'	System	27 Aug 2020 12:50:08



**US3292304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2003'	System	27 Aug 2020 12:50:08

**US3292304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2003'	System	27 Aug 2020 12:50:08

**US3292304**

**Folder: Screening**

**Form: Medical History (6)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2003'	System	27 Aug 2020 12:50:08

US3292304

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 10:59:24
DataPoint Un-verified.		01 Oct 2020 16:43:25
DataPoint Verified.		01 Oct 2020 16:35:42
		01 Oct 2020 16:35:01
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	22 Sep 2020 20:57:12
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:59:03
User coded data point as SOC: Investigations, HLGT: Gastrointestinal investigations, HLT: Gastrointestinal and abdominal imaging procedures, PT: Colonoscopy, LLT: Colonoscopy - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:56
Data point term sent to Coder	System	27 Aug 2020 12:51:11
User entered 'colonoscopy'	(b) (4), (b) (6)	27 Aug 2020 12:50:25

US3292304

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:43:47
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un Apr 2019'	(b) (4), (b) (6)	27 Aug 2020 12:50:25

US3292304

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:43:48
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:50:25

**US3292304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:43:50
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:50:25

**US3292304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:25:14
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un Apr 2019'	(b) (4), (b) (6)	27 Aug 2020 12:50:25



US3292304

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:43:52
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'		27 Aug 2020 12:50:25

**US3292304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Apr 2019'	System	27 Aug 2020 12:50:25

**US3292304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2019'	System	27 Aug 2020 12:50:25

**US3292304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Apr 2019'	System	27 Aug 2020 12:50:25

**US3292304**

**Folder: Screening**

**Form: Medical History (7)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2019'	System	27 Aug 2020 12:50:25

US3292304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'Per DM CLR: Please specify the location of Polyp. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	26 Oct 2020 10:59:19
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Large intestinal polypectomy, LLT: Colon polypectomy - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 06:39:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Oct 2020 06:39:25
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:33:43
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
Data point term sent to Coder		22 Sep 2020 20:58:33
Query 'Per DM CLR: Please specify the location of Polyp. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	22 Sep 2020 20:57:50
Coding entries removed.	Dawn Killian (b) (4)	22 Sep 2020 20:57:45
User entered 'SMALL POLYP REMOVAL in colon' reason for change: Data Entry Error	Dawn Killian (b) (4)	22 Sep 2020 20:57:45
User opened query 'Per DM CLR: Please specify the location of Polyp. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:59:11

US3292304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:09

Condition

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLG: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Polypectomy, LLT: Polyp removal - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:21:26
Data point term sent to Coder	System	27 Aug 2020 12:51:12
User entered 'small polyp removal'	(b) (4), (b) (6)	27 Aug 2020 12:50:44

US3292304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:45
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un Apr 2019'	(b) (4), (b) (6)	27 Aug 2020 12:50:44



US3292304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:46
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:50:44

US3292304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:48
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:50:44

**US3292304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:49
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un Apr 2019'	(b) (4), (b) (6)	27 Aug 2020 12:50:44

US3292304

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:33:51
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:50:44

**US3292304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Apr 2019'	System	27 Aug 2020 12:50:44

**US3292304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2019'	System	27 Aug 2020 12:50:44

**US3292304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Apr 2019'	System	27 Aug 2020 12:50:44

**US3292304**

**Folder: Screening**

**Form: Medical History (8)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2019'	System	27 Aug 2020 12:50:44



US3292304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Oct 2020 11:00:25
DataPoint Un-verified.		01 Oct 2020 16:45:31
DataPoint Verified.		01 Oct 2020 16:35:42
		01 Oct 2020 16:35:01
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' answered with 'stomach pain' (Site from DM).	Dawn Killian (b) (4)	22 Sep 2020 20:58:02
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF. Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:59:23
User coded data point as SOC: Investigations, HLGT: Investigations, imaging and histopathology procedures NEC, HLT: Imaging procedures NEC, PT: Endoscopy, LLT: Endoscopy - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:56
Data point term sent to Coder	System	27 Aug 2020 12:51:12
User entered 'ENDOSCOPY'	(b) (4), (b) (6)	27 Aug 2020 12:50:59

US3292304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:33
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'UN UNK 2007'	(b) (4), (b) (6)	27 Aug 2020 12:50:59

US3292304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:35
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:50:59

US3292304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:36
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:50:59

**US3292304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:38
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered 'UN UNK 2007'		27 Aug 2020 12:50:59

US3292304

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:45:39
DataPoint Verified.		01 Oct 2020 16:35:42
User entered '0'		01 Oct 2020 16:35:01
		27 Aug 2020 12:50:59

**US3292304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2007'	System	27 Aug 2020 12:50:59

**US3292304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2007'	System	27 Aug 2020 12:50:59



**US3292304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2007'	System	27 Aug 2020 12:50:59

**US3292304**

**Folder: Screening**

**Form: Medical History (9)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2007'	System	27 Aug 2020 12:50:59

US3292304

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.	(b) (4)	09 Mar 2021 16:25:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4)	19 Jan 2021 20:34:52
DataPoint Verified.	(b) (4), (b) (6)	19 Jan 2021 20:34:44
User closed query 'Please add 'STEROID INJECTION' to Med Hx to capture the the event noted in source as "inflamed disks in back [due to motorcycle accident] is the indication for which the steroids were given. ' (Site from CRA).	(b) (4)	19 Jan 2021 20:34:41
User closed query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	(b) (4)	30 Nov 2020 20:45:57
' (Site from DM).	(b) (4)	
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Intrathecal injection, LLT: Intrathecal injection - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 08:37:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	15 Oct 2020 08:37:29
Data point term sent to Coder	System	05 Oct 2020 15:49:19
Query 'Please add 'STEROID INJECTION' to Med Hx to capture the the event noted in source as "inflamed disks in back [due to motorcycle accident] is the indication for which the steroids were given. ' answered with 'updated' (Site from CRA).	(b) (4), (b) (6)	05 Oct 2020 15:49:17
Coding entries removed.	(b) (4)	05 Oct 2020 15:49:07
User entered 'Steroid injection due to INFLAMMED DISKS IN BACK due to motorcycle accident' reason for change: Data Entry Error	(b) (4)	05 Oct 2020 15:49:07

US3292304

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:09

Condition

Audit	User	Time (GMT)
User opened query 'Please add 'STEROID INJECTION' to Med Hx to capture the the event noted in source as "inflamed disks in back [due to motorcycle accident] is the indication for which the steroids were given. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 17:26:43
DataPoint Verified.		01 Oct 2020 16:48:08
DataPoint Un-verified.		01 Oct 2020 16:47:36
DataPoint Verified.		01 Oct 2020 16:35:42
		01 Oct 2020 16:35:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Bone disorders (excl congenital and fractures), HLT: Bone disorders NEC, PT: Osteitis, LLT: Bone inflammation - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 11:54:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	29 Sep 2020 11:54:03
Data point term sent to Coder	System	22 Sep 2020 21:02:36
Query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	Dawn Killian (b) (4)	22 Sep 2020 21:01:48
' answered with 'updated' (Site from DM).		
Coding entries removed.	Dawn Killian (b) (4)	22 Sep 2020 21:01:44
User entered 'Inflamed disks in back' reason for change: Data Entry Error	Dawn Killian (b) (4)	22 Sep 2020 21:01:44
User opened query 'Per DM CLR: Please update MH term to reflect a medical condition/diagnosis as appropriate. Please reconcile with the Con Med eCRF as necessary.	(b) (4), (b) (6)	16 Sep 2020 14:59:31
' (Site from DM).		
User coded data point as SOC: Surgical and medical procedures, HLGT: Endocrine gland therapeutic procedures, HLT: Hormonal therapeutic procedures NEC, PT: Steroid therapy, LLT: Steroid therapy - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 14:49:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 14:49:41
Data point term sent to Coder	System	27 Aug 2020 12:52:15

PRODUCTION RELEASE (v12.003  
EAB) (1725)

495 of 2331

US3292304

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
User entered 'STEROID INJECTION'	(b) (4), (b) (6)	27 Aug 2020 12:51:13

**US3292304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.	(b) (4)	09 Mar 2021 16:25:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 16:48:15
DataPoint Verified.	(b) (4)	01 Oct 2020 16:47:39
DataPoint Un-verified.	(b) (4)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4)	01 Oct 2020 16:35:01
User entered 'UN UNK 2005'	(b) (4)	27 Aug 2020 12:51:13

US3292304

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.		09 Mar 2021 16:25:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:48:10
DataPoint Verified.		01 Oct 2020 16:47:43
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'		27 Aug 2020 12:51:13

US3292304

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.		09 Mar 2021 16:26:13
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:48:13
DataPoint Verified.		01 Oct 2020 16:47:45
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered 'No (N)'		27 Aug 2020 12:51:13



**US3292304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.	(b) (4)	09 Mar 2021 16:26:22
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 16:48:12
DataPoint Verified.	(b) (4)	01 Oct 2020 16:47:47
DataPoint Un-verified.	(b) (4)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4)	01 Oct 2020 16:35:01
User entered 'UN UNK 2005'	(b) (4)	27 Aug 2020 12:51:13

US3292304

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.		09 Mar 2021 16:26:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:48:17
DataPoint Verified.		01 Oct 2020 16:47:48
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'		27 Aug 2020 12:51:13

**US3292304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2005'	System	27 Aug 2020 12:51:13

**US3292304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2005'	System	27 Aug 2020 12:51:13

**US3292304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2005'	System	27 Aug 2020 12:51:13

**US3292304**

**Folder: Screening**

**Form: Medical History (10)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2005'	System	27 Aug 2020 12:51:13

US3292304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:35:18
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Dental and gingival therapeutic procedures, PT: Wisdom teeth removal, LLT: Wisdom teeth removal - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:04:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	(b) (4)	27 Aug 2020 19:04:58
Data point term sent to Coder	System	27 Aug 2020 12:52:12
User entered 'WISDOM TEETH REMOVAL'	(b) (4), (b) (6)	27 Aug 2020 12:51:36

US3292304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:35:19
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'UN UNK 2004'	(b) (4), (b) (6)	27 Aug 2020 12:51:36



US3292304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:35:21
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:51:36

US3292304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:35:22
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered 'No (N)'		27 Aug 2020 12:51:36

**US3292304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:35:25
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered 'UN UNK 2004'		27 Aug 2020 12:51:36

US3292304

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:35:26
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:51:36

**US3292304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2004'	System	27 Aug 2020 12:51:36

**US3292304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2004'	System	27 Aug 2020 12:51:36

**US3292304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2004'	System	27 Aug 2020 12:51:36

**US3292304**

**Folder: Screening**

**Form: Medical History (11)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2004'	System	27 Aug 2020 12:51:36



US3292304

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4) (h) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:42:22
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Musculoskeletal and connective tissue disorders congenital, HLT: Musculoskeletal and connective tissue disorders of face, neck and jaw congenital, PT: Cleft lip, LLT: Cleft lip - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:05:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:05:02
Data point term sent to Coder	System	27 Aug 2020 12:52:14
User entered 'CLEFT LIP'	(b) (4), (b) (6)	27 Aug 2020 12:51:49

US3292304

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:06
User closed query 'Per source, Date is UN UNK 1985. Please review and reconcile.' (Site from CRA).	(b) (4)	16 Apr 2021 17:58:04
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:58:00
User closed query 'Start date is prior to Date of Birth. System Please correct.' (Site from System).		17 Mar 2021 21:39:34
User entered (b) (6) 1985' reason for change: Data Entry Error	Kristy Trevino (b) (4)	17 Mar 2021 21:39:34
Query 'Per source, Date is UN UNK 1985. Please review and reconcile.' answered with 'Corrected ' (Site from CRA).	(b) (4)	
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	Kristy Trevino (b) (4)	17 Mar 2021 21:27:25
Signature has been broken.	(b) (4)	
User entered 'UN UNK 1985' reason for change: Data Entry Error	System	17 Mar 2021 21:27:08
User opened query 'Per source, Date is UN UNK 1985. Please review and reconcile.' (Site from CRA).	Kristy Trevino (b) (4)	17 Mar 2021 21:27:08
User signature succeeded.	(b) (4)	17 Mar 2021 21:27:08
DataPoint Un-verified.	(b) (4), (b) (6)	09 Mar 2021 16:26:50
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 14:08:28
User closed query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	(b) (4)	01 Oct 2020 16:35:42
User entered 'UN (b) (6) 1985' reason for change: Data Entry Error	(b) (4)	01 Oct 2020 16:35:01
User opened query 'Start date is prior to Date of Birth. Please correct.' (Site from System).	Dawn Killian (b) (4)	22 Sep 2020 21:02:15
User entered 'UN UNK 1985'	(b) (4)	22 Sep 2020 21:02:15
	System	27 Aug 2020 12:51:49
	(b) (4), (b) (6)	27 Aug 2020 12:51:49

US3292304

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:42:27
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:51:49

US3292304

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:42:25
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered 'No (N)'		27 Aug 2020 12:51:49

US3292304

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:06
User closed query 'Per source, Date is UN UNK 1985. Please review and reconcile.' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.		16 Apr 2021 17:58:05
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).		16 Apr 2021 17:58:02
User closed query 'Stop date is prior to Start date. Please correct.' (Site from System).		18 Mar 2021 14:16:16
User entered '(b) (6) 1985' reason for change: Data Entry Error	Kristy Trevino (b) (4)	18 Mar 2021 14:16:16
User opened query 'Stop date is prior to Start date. Please correct.' (Site from System).	(b) (4)	System
Query 'Per source, Date is UN UNK 1985. Please review and reconcile.' answered with 'Corrected' (Site from CRA).		17 Mar 2021 21:39:34
Signature has been broken.	Kristy Trevino (b) (4)	17 Mar 2021 21:27:33
User entered 'UN UNK 1985' reason for change: Data Entry Error	Kristy Trevino (b) (4)	17 Mar 2021 21:27:08
User opened query 'Per source, Date is UN UNK 1985. Please review and reconcile.' (Site from CRA).	(b) (4)	17 Mar 2021 21:27:08
User signature succeeded.	(b) (4), (b) (6)	09 Mar 2021 16:26:54
DataPoint Un-verified.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User entered 'UN (b) (6) 1985' reason for change: Data Entry Error		01 Oct 2020 16:35:42
User entered 'UN UNK 1985'	Dawn Killian (b) (4)	01 Oct 2020 16:35:01
	(b) (4)	22 Sep 2020 21:02:15
	(b) (4), (b) (6)	27 Aug 2020 12:51:49

US3292304

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:42:31
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'		27 Aug 2020 12:51:49

US3292304

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered (b) (6) 1985'	System	17 Mar 2021 21:39:34
User entered 'Jan 1985'	System	17 Mar 2021 21:27:08
User entered (b) (6) 1985'	System	22 Sep 2020 21:02:15
User entered 'Jan 1985'	System	27 Aug 2020 12:51:49

**US3292304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '1985'	System	27 Aug 2020 12:51:49



US3292304

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered (b) (6) 1985'	System	18 Mar 2021 14:16:16
User entered 'Jan 1985'	System	17 Mar 2021 21:27:08
User entered (b) (6) 1985'	System	22 Sep 2020 21:02:15
User entered 'Jan 1985'	System	27 Aug 2020 12:51:49

**US3292304**

**Folder: Screening**

**Form: Medical History (12)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '1985'	System	27 Aug 2020 12:51:49

US3292304

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:09
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Diverticular disorders, HLT: Diverticula, PT: Diverticulum, LLT: Diverticulosis - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:03
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	27 Aug 2020 19:05:03
Data point term sent to Coder	System	27 Aug 2020 12:53:16
User entered 'DIVERTICULOSIS'	(b) (4), (b) (6)	27 Aug 2020 12:52:31

**US3292304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:12
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'UN Mar 2019'	(b) (4), (b) (6)	27 Aug 2020 12:52:31

US3292304

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:16
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:52:31

**US3292304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:14
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 12:52:31

**US3292304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:17
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 12:52:31

US3292304

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:45:19
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:52:31



**US3292304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Mar 2019'	System	27 Aug 2020 12:52:31

**US3292304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2019'	System	27 Aug 2020 12:52:31

**US3292304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:52:31

**US3292304**

**Folder: Screening**

**Form: Medical History (13)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:52:31

US3292304

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:11
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Intervertebral disc disorders NEC, PT: Intervertebral disc protrusion, LLT: Intervertebral disc bulging - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:20:09
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:20:09
Data point term sent to Coder	System	27 Aug 2020 12:53:15
User entered 'L4-L5 Bulging discs'	(b) (4), (b) (6)	27 Aug 2020 12:53:07

US3292304

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:13
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un UNK 2005'	(b) (4), (b) (6)	27 Aug 2020 12:53:07

US3292304

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:15
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:53:07

**US3292304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:17
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:53:07



**US3292304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:18
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un UNK 2005'	(b) (4), (b) (6)	27 Aug 2020 12:53:07

US3292304

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:28:20
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:53:07

**US3292304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2005'	System	27 Aug 2020 12:53:07

**US3292304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2005'	System	27 Aug 2020 12:53:07

**US3292304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2005'	System	27 Aug 2020 12:53:07

**US3292304**

**Folder: Screening**

**Form: Medical History (14)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2005'	System	27 Aug 2020 12:53:07

US3292304

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'Per DM CLR: Please update the condition to include the laterality of Torn Meniscus (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	08 Oct 2020 14:26:48
DataPoint Verified.		01 Oct 2020 17:34:50
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear of knee - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 21:11:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 21:11:43
Data point term sent to Coder	System	22 Sep 2020 21:10:44
Query 'Per DM CLR: Please update the condition to include the laterality of Torn Meniscus (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	22 Sep 2020 21:10:10
Coding entries removed.	Dawn Killian (b) (4)	22 Sep 2020 21:10:04
User entered 'TORN MENISCUS right Knee' reason for change: Data Entry Error	Dawn Killian (b) (4)	22 Sep 2020 21:10:04
User opened query 'Per DM CLR: Please update the condition to include the laterality of Torn Meniscus (e.g. Left, Right or Bilateral). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	16 Sep 2020 14:59:48

US3292304

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Bone and joint injuries NEC, PT: Meniscus injury, LLT: Meniscus tear - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:20
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:20
Data point term sent to Coder	System	27 Aug 2020 12:54:16
User entered 'torn meniscus'	(b) (4), (b) (6)	27 Aug 2020 12:53:48



**US3292304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:34:52
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un UNK 2003'	(b) (4), (b) (6)	27 Aug 2020 12:53:48

US3292304

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:34:54
DataPoint Un-verified.	(b) (4), (b) (6)	1 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	1 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	7 Aug 2020 12:53:48

**US3292304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:30:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:34:55
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:53:48

US3292304

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:34:57
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un UNK 2003'	(b) (4), (b) (6)	27 Aug 2020 12:53:48

US3292304

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:34:58
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:53:48

**US3292304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2003'	System	27 Aug 2020 12:53:48

**US3292304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2003'	System	27 Aug 2020 12:53:48

**US3292304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2003'	System	27 Aug 2020 12:53:48



**US3292304**

**Folder: Screening**

**Form: Medical History (15)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2003'	System	27 Aug 2020 12:53:48

US3292304

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:44:25
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
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)	27 Aug 2020 19:05:20
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:20
	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 12:54:17
User entered 'depression'	(b) (4), (b) (6)	27 Aug 2020 12:53:58

US3292304

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:44:31
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'un Jan 2020'	(b) (4), (b) (6)	27 Aug 2020 12:53:58

US3292304

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4) (h) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:44:27
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'		27 Aug 2020 12:53:58

US3292304

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:44:34
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 12:53:58

**US3292304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:44:35
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered empty.		27 Aug 2020 12:53:58

US3292304

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:44:39
DataPoint Verified.		01 Oct 2020 16:35:42
User entered '0'		01 Oct 2020 16:35:01
		27 Aug 2020 12:53:58

**US3292304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2020'	System	27 Aug 2020 12:53:58



**US3292304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2020'	System	27 Aug 2020 12:53:58

**US3292304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:53:58

**US3292304**

**Folder: Screening**

**Form: Medical History (16)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:53:58

US3292304

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:30:09

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'Per DM CLR: Please specify the location and/or type of Acne. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	08 Oct 2020 14:27:20
' (Site from DM).		
DataPoint Verified.		01 Oct 2020 16:36:00
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:32:14
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 21:11:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 21:11:42
Data point term sent to Coder	System	22 Sep 2020 21:10:46
Query 'Per DM CLR: Please specify the location and/or type of Acne. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Dawn Killian (b) (4)	22 Sep 2020 21:10:41
' answered with 'updated' (Site from DM).		
Coding entries removed.	Dawn Killian (b) (4)	22 Sep 2020 21:10:35
User entered 'ADULT Facial ACNE' reason for change: Data Entry Error	Dawn Killian (b) (4)	22 Sep 2020 21:10:35
User opened query 'Per DM CLR: Please specify the location and/or type of Acne. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	16 Sep 2020 14:59:59
' (Site from DM).		
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Skin appendage conditions, HLT: Acnes, PT: Acne, LLT: Acne - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:05:21

US3292304

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	27 Aug 2020 19:05:21
User: Coder System - version MedDRA\\23.0.	(b) (4)	
Data point term sent to Coder	System	27 Aug 2020 12:54:16
User entered 'adult acne'	(b) (4), (b) (6)	27 Aug 2020 12:54:11

US3292304

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:36:01
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:32:15
User entered 'un UNK 2000'	(b) (4), (b) (6)	27 Aug 2020 12:54:11

US3292304

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:36:03
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:32:26
User entered '0'		27 Aug 2020 12:54:11

**US3292304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:30:09**

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:36:05
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:32:29
User entered 'Yes (Y)'		27 Aug 2020 12:54:11



**US3292304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:36:06
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:34:20
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 12:54:11

US3292304

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:36:08
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:42
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:35:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:54:11

**US3292304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2000'	System	27 Aug 2020 12:54:11

**US3292304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2000'	System	27 Aug 2020 12:54:11

**US3292304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:54:11

**US3292304**

**Folder: Screening**

**Form: Medical History (17)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered empty.	System	27 Aug 2020 12:54:11

US3292304

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:30:09

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:34:19
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal signs and symptoms, HLT: Gastrointestinal and abdominal pains (excl oral and throat), PT: Abdominal pain upper, LLT: Stomach pain - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 21:00:47
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	22 Sep 2020 21:00:47
Data point term sent to Coder	System	22 Sep 2020 20:59:34
User entered 'stomach pain'	Dawn Killian (b) (4)	22 Sep 2020 20:59:08
	(b) (4)	

US3292304

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:34:20
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered 'UN UNK 2007'	Dawn Killian (b) (4)	22 Sep 2020 20:59:08
	(b) (4)	



US3292304

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:34:22
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'	Dawn Killian (b) (4)	22 Sep 2020 20:59:08
	(b) (4)	

US3292304

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:30:09

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:34:23
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered 'No (N)'	Dawn Killian (b) (4)	22 Sep 2020 20:59:08
	(b) (4)	

US3292304

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:34:25
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered 'UN UNK 2007'	Dawn Killian (b) (4)	22 Sep 2020 20:59:08
	(b) (4)	

US3292304

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:30:09

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:34:26
DataPoint Un-verified.		01 Oct 2020 16:35:42
DataPoint Verified.		01 Oct 2020 16:35:01
User entered '0'	Dawn Killian (b) (4)	22 Sep 2020 20:59:08
	(b) (4)	

**US3292304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2007'	System	22 Sep 2020 20:59:08

**US3292304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2007'	System	22 Sep 2020 20:59:08

**US3292304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'Jan 2007'	System	22 Sep 2020 20:59:08

**US3292304**

**Folder: Screening**

**Form: Medical History (19)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '2007'	System	22 Sep 2020 20:59:08



**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:38:07
User entered 'Yes (Y)'		7 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 17:38:42
User entered '25 Aug 2020'		27 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 17:38:46
User entered '11:13'		27 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered '25 Aug 2020 11:13'	System	27 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:38:49
User entered '173.9' cm		27 Aug 2020 12:55:28
DataPoint set to visible.	System	25 Aug 2020 19:26:11

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:38:52
User entered '79.2' kg		27 Aug 2020 12:55:28
DataPoint set to visible.	System	25 Aug 2020 19:26:11

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
Amendment Manager: User entered '26.18943'	System	17 Sep 2020 00:02:02
User entered '26.2'	System	27 Aug 2020 12:55:28
DataPoint set to visible.	System	25 Aug 2020 19:26:11

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'kg/m2'	System	27 Aug 2020 12:55:28
DataPoint set to visible.	System	25 Aug 2020 19:26:11



**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:39:09
User entered missing code ND - Not Done.		27 Aug 2020 12:55:28

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
DataPoint Verified.	(b) (4)	09 Mar 2021 16:33:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 13:33:11
Query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	21 Dec 2020 19:54:03
DataPoint Un-verified.	(b) (4)	21 Dec 2020 19:53:58
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4)	21 Dec 2020 19:53:58
User opened query 'Per CDM: Please remove data from this field, as this should be 'blank' if 'Temperature' is Not Done. Thanks ' (Site from DM).	(b) (4), (b) (6)	14 Dec 2020 17:20:24
DataPoint Verified.	(b) (4)	1 Oct 2020 17:39:10
User entered 'Other (Other)'	(b) (4)	7 Aug 2020 12:55:28

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'Per CDM: Please remove the data as this field should be "blank".	(b) (4)	30 Dec 2020 21:51:24
' (Site from DM).	(b) (4), (b) (6)	
Query 'Per CDM: Please remove the data as this field should be "blank".		30 Dec 2020 17:39:36
' answered with 'If field is blank, queried "Data is required."' (Site from DM).		
User opened query 'Per CDM: Please remove the data as this field should be "blank".		23 Dec 2020 13:33:23
' (Site from DM).		
DataPoint Verified.		01 Oct 2020 17:39:12
User entered missing code ND - Not Done.		27 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 17:39:14
User entered missing code ND - Not Done.		27 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'bpm'	System	27 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:39:16
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 12:55:28

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'breaths/min'	System	27 Aug 2020 12:55:28

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:39:17
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 12:55:28



**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'mmHg'	System	27 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:39:19
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 12:55:28

**US3292304**

**Folder: Screening**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User entered 'mmHg'	System	27 Aug 2020 12:55:28

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40

US3292304

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40

US3292304

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'per source HEENT in the "Description of Abnormality (comments required if abnormal or not done)" section lists "cleft pallet repair" yet HEENT is marked as "Normal." please confirm Abnormal status as NCS or CS.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Jan 2021 20:35:13
Query 'per source HEENT in the "Description of Abnormality (comments required if abnormal or not done)" section lists "cleft pallet repair" yet HEENT is marked as "Normal." please confirm Abnormal status as NCS or CS.' answered with 'left pallet repaired; normal per INV' (Site from CRA).	Dawn Killian (b) (4) (b) (4)	08 Oct 2020 19:35:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:48:43
DataPoint Un-verified.		01 Oct 2020 17:48:38
User opened query 'per source HEENT in the "Description of Abnormality (comments required if abnormal or not done)" section lists "cleft pallet repair" yet HEENT is marked as "Normal." please confirm Abnormal status as NCS or CS.' (Site from CRA).		01 Oct 2020 17:48:32
DataPoint Verified.		01 Oct 2020 17:43:51
User entered 'Yes (Y)'		27 Aug 2020 12:55:46

**US3292304**

**Folder: Screening**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:30:09**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:43:54
User entered '25 Aug 2020'		27 Aug 2020 12:55:46

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:27:54
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:56:11



US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'Yes (Y)'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'No (N)'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'No (N)'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'No (N)'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

[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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'No (N)'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:27:54
User entered 'No (N)'	(b) (4), (b) (6)	7 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'No (N)'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'No (N)'		27 Aug 2020 12:56:11



US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:27:54
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'No (N)'		27 Aug 2020 12:56:11

**US3292304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:30:09**

**Other**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'No (N)'		27 Aug 2020 12:56:11

**US3292304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:30:09**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:27:54
User entered empty.	(b) (4), (b) (6)	7 Aug 2020 12:56:11

**US3292304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:30:09**

**No Risk Identified**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 16:27:54
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered '0'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

**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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered '0'		27 Aug 2020 12:56:11



US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

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)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered '0'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered 'l'		27 Aug 2020 12:56:11

US3292304

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:30:09

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 12:56:11

**US3292304**

**Folder: Screening**

**Form: Risk of Exposure**

**Generated On: 09 Jun 2021 16:30:09**

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 09:59:40
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 16:27:54
User entered empty.		27 Aug 2020 12:56:11

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 17:56:10
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:22:41

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 17:56:11
User entered '25 Aug 2020'		27 Aug 2020 15:22:41

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[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 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 17:56:23
User entered 'Clinic (Clinic)'		27 Aug 2020 15:22:41

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'VISIT1'	System	27 Aug 2020 15:22:41



US3292304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:38
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 18:29:43

US3292304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:45:40
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 17:56:18
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 17:56:16
User entered '108329'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 18:29:43

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:45:45
User entered '>=18 and <65 years and not at risk (1)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 18:29:43

US3292304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:09

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 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:45:58
User entered 'No (N)'		27 Aug 2020 15:23:00

US3292304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:09

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 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:46:00
User entered 'No (N)'		27 Aug 2020 15:23:00

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:46:01
User entered 'No (N)'		27 Aug 2020 15:23:00

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:30:09**

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:46:03
User entered 'No (N)'		27 Aug 2020 15:23:00

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Randomization**

**Generated On: 09 Jun 2021 16:30:09**

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:46:04
User entered 'No (N)'		27 Aug 2020 15:23:00



US3292304

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:30:09

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
DataPoint Verified.	(b) (4)	02 Mar 2021 19:27:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	11 Dec 2020 15:31:07
Query 'Per CDM: This field requires a Yes or No response. Please complete.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:16:06
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:16:02
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4) (b) (4), (b) (6)	01 Dec 2020 22:14:59
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:51:10
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:51:09

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:30:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 18:49:54
User entered missing code ND - Not Done.		27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:30:09**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 18:49:55
User entered missing code ND - Not Done.		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:30:09

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 18:49:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:30:09**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 18:49:55
User entered missing code ND - Not Done.		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User accepted default value 'Pre-Dose (PREDOSE)'	(b) (4), (b) (6)	7 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:58:11
User entered 'Yes (Y)'		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:58:14
User entered '25 Aug 2020'		27 Aug 2020 15:24:15



**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 18:58:16
User entered '12:05'	(b) (4), (b) (6)	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered '25 Aug 2020 12:05'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:58:39
User entered '036.1' C		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:58:45
User entered 'Oral (Oral)'		27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:30:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:58:48
User entered empty.		27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 18:58:50
User entered '075'		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'bpm'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:58:53
User entered '015'		27 Aug 2020 15:24:15



US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'breaths/min'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:58:58
User entered '131'		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'mmHg'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 18:59:52
User entered '089'	(b) (4), (b) (6)	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'mmHg'	System	27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:30:09**

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 18:49:54
User entered missing code ND - Not Done.		27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing**

**Generated On: 09 Jun 2021 16:30:09**

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 18:49:55
User entered missing code ND - Not Done.		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User accepted default value 'Post-Dose (POSTDOSE)'		27 Aug 2020 15:24:15



US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:02:06
User entered 'Yes (Y)'		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:02:09
User entered '25 Aug 2020'		27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 19:02:32
User entered '14:21'	(b) (4), (b) (6)	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered '25 Aug 2020 14:21'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:02:38
User entered '36.5' C		27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:02:40
User entered 'Oral (Oral)'		27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:30:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:33:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:15

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:02:47
User entered '80'		27 Aug 2020 15:24:15



US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'bpm'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 19:02:51
User entered '20'	(b) (4), (b) (6)	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'breaths/min'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 19:02:54
User entered '128'	(b) (4), (b) (6)	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'mmHg'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:02:56
User entered '87'		7 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'mmHg'	System	27 Aug 2020 15:24:15

US3292304

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:09

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:15:43
User entered 'No (N)'		27 Aug 2020 15:24:20



**US3292304**

**Folder: Visit 1 Day 1**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:30:09**

**Date of examination** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 19:15:45
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:20

US3292304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 19:16:05
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 19:26:39

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:30:09**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:16:06
User entered empty.		25 Aug 2020 19:26:39

US3292304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

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 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:16:09
User entered empty.		25 Aug 2020 19:26:39

US3292304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 19:26:39

US3292304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:16:28
User entered '25 Aug 2020'		25 Aug 2020 19:26:39

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:30:09**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 19:16:25
User entered '13:42'	(b) (4), (b) (6)	25 Aug 2020 19:26:39

US3292304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered '25 Aug 2020 13:42'	System	25 Aug 2020 19:26:39



US3292304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 19:16:31
User entered 'Left Arm (LEFT ARM)'	(b) (4), (b) (6)	25 Aug 2020 19:26:39

US3292304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:16:33
User entered 'ONCE'	System	25 Aug 2020 19:26:39

US3292304

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:17:09
User entered 'Yes (Y)'		27 Aug 2020 15:24:40

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:17:13
User entered '25 Aug 2020'		27 Aug 2020 15:24:40

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:17:15
User entered '12:11'		7 Aug 2020 15:24:40

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered '25 Aug 2020 12:11'	System	27 Aug 2020 15:24:40

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab**

**Generated On: 09 Jun 2021 16:30:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:31:35
User entered '25 Aug 2020'		27 Aug 2020 15:24:56



**US3292304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		27 Aug 2020 15:24:56

US3292304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	01 Oct 2020 21:13:36
DataPoint Un-verified.	(b) (4), (b) (6)	01 Oct 2020 21:13:33
DataPoint Verified.		01 Oct 2020 19:27:46
User entered 'Yes (Y)'		27 Aug 2020 15:24:56

US3292304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:30:09

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:46:42
Query 'please confirm collection time as the time recorded in EDC is after dose of IP and not congruent with time of collection per source.' canceled (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 20:46:40
User opened query 'please confirm collection time as the time recorded in EDC is after dose of IP and not congruent with time of collection per source.' (Site from CRA).	(b) (4), (b) (6)	01 Oct 2020 19:31:24
User entered '12:32'	(b) (4), (b) (6)	27 Aug 2020 15:24:56

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered '25 Aug 2020 12:32'	System	27 Aug 2020 15:24:56

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	27 Aug 2020 15:24:56

US3292304

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
DataPoint Verified.		09 Mar 2021 16:33:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:24:56

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:30:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
DataPoint Verified.		09 Mar 2021 16:33:57
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:24:56

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered empty.	System	27 Aug 2020 15:24:56



**US3292304**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:31:54
User entered 'Yes (Y)'		27 Aug 2020 15:25:01

**US3292304**

**Folder: Visit 1 Day 1**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'I'	System	27 Aug 2020 15:25:01

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:03', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1fc5f147-072f-45d2-a80a-77e835c42252'	System	25 Aug 2020 19:27:38
User entered 'Yes (Y)'	System	25 Aug 2020 19:27:38

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:07', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1fc5f147-072f-45d2-a80a-77e835c42252'	System	25 Aug 2020 19:27:38
User entered '97.7'	System	25 Aug 2020 19:27:38

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:11', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1fc5f147-072f-45d2-a80a-77e835c42252'	System	25 Aug 2020 19:27:38
User entered 'No (N)'	System	25 Aug 2020 19:27:38

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:15', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1fc5f147-072f-45d2-a80a-77e835c42252'	System	25 Aug 2020 19:27:38
User entered '25 Aug 2020 14:27'	System	25 Aug 2020 19:27:38

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 14:02'	System	25 Aug 2020 19:26:39



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 16:32'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:29:17', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '95de2693-2a02-47c0-a76c-99170d08f78e'	System	26 Aug 2020 03:30:38
User entered 'Yes (Y)'	System	26 Aug 2020 03:30:38

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:30:26', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '95de2693-2a02-47c0-a76c-99170d08f78e'	System	26 Aug 2020 03:30:38
User entered '98.4'	System	26 Aug 2020 03:30:38

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:30:30', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '95de2693-2a02-47c0-a76c-99170d08f78e'	System	26 Aug 2020 03:30:38
User entered 'No (N)'	System	26 Aug 2020 03:30:38

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:30:35', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '95de2693-2a02-47c0-a76c-99170d08f78e'	System	26 Aug 2020 03:30:38
User entered '25 Aug 2020 22:30'	System	26 Aug 2020 03:30:38

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:26:39



US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 2'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:23:54', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f3284133-24c9-4c8d-8e65-3f72c4b7493f'	System	27 Aug 2020 03:24:08
User entered 'Yes (Y)'	System	27 Aug 2020 03:24:08

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:23:58', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f3284133-24c9-4c8d-8e65-3f72c4b7493f' User entered '98.4'	System	27 Aug 2020 03:24:08
	System	27 Aug 2020 03:24:08

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:24:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f3284133-24c9-4c8d-8e65-3f72c4b7493f'	System	27 Aug 2020 03:24:08
User entered 'No (N)'	System	27 Aug 2020 03:24:08

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:24:05', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f3284133-24c9-4c8d-8e65-3f72c4b7493f'	System	27 Aug 2020 03:24:08
User entered '26 Aug 2020 22:24'	System	27 Aug 2020 03:24:08

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 3'	System	25 Aug 2020 19:26:39



US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:31:14', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd82fc5a5-675e-458f-8be5-7ba5053d62f3'	System	28 Aug 2020 03:31:30
User entered 'Yes (Y)'	System	28 Aug 2020 03:31:30

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:31:21', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd82fc5a5-675e-458f-8be5-7ba5053d62f3'	System	28 Aug 2020 03:31:30
User entered '98.7'	System	28 Aug 2020 03:31:30

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:31:24', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd82fc5a5-675e-458f-8be5-7ba5053d62f3'	System	28 Aug 2020 03:31:30
User entered 'No (N)'	System	28 Aug 2020 03:31:30

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:31:26', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd82fc5a5-675e-458f-8be5-7ba5053d62f3'	System	28 Aug 2020 03:31:30
User entered '27 Aug 2020 22:31'	System	28 Aug 2020 03:31:30

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 4'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:11', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '49ca6e33-e3a2-4b60-9ab5-1beea8b2a4fe'	System	29 Aug 2020 03:28:34
User entered 'Yes (Y)'	System	29 Aug 2020 03:28:34



US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:15', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '49ca6e33-e3a2-4b60-9ab5-1beea8b2a4fe'	System	29 Aug 2020 03:28:34
User entered '97.8'	System	29 Aug 2020 03:28:34

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:25', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '49ca6e33-e3a2-4b60-9ab5-1beea8b2a4fe'	System	29 Aug 2020 03:28:34
User entered 'No (N)'	System	29 Aug 2020 03:28:34

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:29', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '49ca6e33-e3a2-4b60-9ab5-1beea8b2a4fe'	System	29 Aug 2020 03:28:34
User entered '28 Aug 2020 22:28'	System	29 Aug 2020 03:28:34

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 5'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:28', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '43587b13-a02f-4197-a4b4-886012eabe8b'	System	30 Aug 2020 00:46:40
User entered 'Yes (Y)'	System	30 Aug 2020 00:46:40

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:31', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '43587b13-a02f-4197-a4b4-886012eabe8b' User entered '97.4'	System	30 Aug 2020 00:46:40
	System	30 Aug 2020 00:46:40



US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:33', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '43587b13-a02f-4197-a4b4-886012eabe8b'	System	30 Aug 2020 00:46:40
User entered 'No (N)'	System	30 Aug 2020 00:46:40

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:36', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '43587b13-a02f-4197-a4b4-886012eabe8b'	System	30 Aug 2020 00:46:40
User entered '29 Aug 2020 19:46'	System	30 Aug 2020 00:46:40

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 6'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:29', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7856345d-3601-4da3-aa05-f5c52ecb1b10'	System	31 Aug 2020 02:32:42
User entered 'Yes (Y)'	System	31 Aug 2020 02:32:42

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:33', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7856345d-3601-4da3-aa05-f5c52ecb1b10'	System	31 Aug 2020 02:32:42
User entered '97.4'	System	31 Aug 2020 02:32:42

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:36', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7856345d-3601-4da3-aa05-f5c52ecb1b10'	System	31 Aug 2020 02:32:42
User entered 'No (N)'	System	31 Aug 2020 02:32:42



US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:40', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7856345d-3601-4da3-aa05-f5c52ecb1b10'	System	31 Aug 2020 02:32:42
User entered '30 Aug 2020 21:32'	System	31 Aug 2020 02:32:42

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 7'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:42:50', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd928aa97-fa53-47ae-be82-9f903ad65781'	System	01 Sep 2020 04:43:03
User entered 'Yes (Y)'	System	01 Sep 2020 04:43:03

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:42:54', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd928aa97-fa53-47ae-be82-9f903ad65781'	System	01 Sep 2020 04:43:03
User entered '98.7'	System	01 Sep 2020 04:43:03

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:42:56', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd928aa97-fa53-47ae-be82-9f903ad65781'	System	01 Sep 2020 04:43:03
User entered 'No (N)'	System	01 Sep 2020 04:43:03

US3292304

Folder: Diary Dose 1 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:42:58', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd928aa97-fa53-47ae-be82-9f903ad65781'	System	01 Sep 2020 04:43:03
User entered '31 Aug 2020 23:42'	System	01 Sep 2020 04:43:03



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Temperature\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:25', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6a9d53d4-0500-4371-9f21-22f17abef0ed'	System	25 Aug 2020 19:27:49
User entered 'None (1)'	System	25 Aug 2020 19:27:49

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:28', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6a9d53d4-0500-4371-9f21-22f17abef0ed'	System	25 Aug 2020 19:27:49
User entered 'No (N)'	System	25 Aug 2020 19:27:49

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:32', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6a9d53d4-0500-4371-9f21-22f17abef0ed'	System	25 Aug 2020 19:27:49
User entered 'No (N)'	System	25 Aug 2020 19:27:49

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:40', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6a9d53d4-0500-4371-9f21-22f17abef0ed'	System	25 Aug 2020 19:27:49
User entered 'None (1)'	System	25 Aug 2020 19:27:49

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:43', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6a9d53d4-0500-4371-9f21-22f17abef0ed'	System	25 Aug 2020 19:27:49
User entered '25 Aug 2020 14:27'	System	25 Aug 2020 19:27:49



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 14:02'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 16:32'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:30:59', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c8c29640-0cea-4bc3-80ec-cee2ffe4da66'	System	26 Aug 2020 03:32:22
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 03:32:22

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:31:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c8c29640-0cea-4bc3-80ec-ccc2ffe4da66'	System	26 Aug 2020 03:32:22
User entered 'No (N)'	System	26 Aug 2020 03:32:22

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:31:57', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c8c29640-0cea-4bc3-80ec-ccc2ffe4da66'	System	26 Aug 2020 03:32:22
User entered 'No (N)'	System	26 Aug 2020 03:32:22

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:16', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c8c29640-0cea-4bc3-80ec-ccc2ffe4da66'	System	26 Aug 2020 03:32:22
User entered 'None (1)'	System	26 Aug 2020 03:32:22

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:19', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c8c29640-0cea-4bc3-80ec-ccc2ffe4da66'	System	26 Aug 2020 03:32:22
User entered '25 Aug 2020 22:32'	System	26 Aug 2020 03:32:22



US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 2'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:24:35', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2839847c-c6bc-4fb5-99b3-4c2ac634b1f1'	System	27 Aug 2020 03:26:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 03:26:25

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:04', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2839847c-c6bc-4fb5-99b3-4c2ac634b1f1'	System	27 Aug 2020 03:26:25
User entered 'No (N)'	System	27 Aug 2020 03:26:25

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2839847c-c6bc-4fb5-99b3-4c2ac634b1f1'	System	27 Aug 2020 03:26:25
User entered 'No (N)'	System	27 Aug 2020 03:26:25

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:18', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2839847c-c6bc-4fb5-99b3-4c2ac634b1f1'	System	27 Aug 2020 03:26:25
User entered 'None (1)'	System	27 Aug 2020 03:26:25

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:20', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2839847c-c6bc-4fb5-99b3-4c2ac634b1f1'	System	27 Aug 2020 03:26:25
User entered '26 Aug 2020 22:26'	System	27 Aug 2020 03:26:25



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 3'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:31:31', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '568e6d36-083e-40ad-8a07-535aa627674d'	System	28 Aug 2020 03:32:07
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 03:32:07

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:31:55', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '568e6d36-083e-40ad-8a07-535aa627674d'	System	28 Aug 2020 03:32:07
User entered 'No (N)'	System	28 Aug 2020 03:32:07

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:31:58', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '568e6d36-083e-40ad-8a07-535aa627674d'	System	28 Aug 2020 03:32:07
User entered 'No (N)'	System	28 Aug 2020 03:32:07

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '568e6d36-083e-40ad-8a07-535aa627674d'	System	28 Aug 2020 03:32:07
User entered 'None (1)'	System	28 Aug 2020 03:32:07

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:04', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '568e6d36-083e-40ad-8a07-535aa627674d'	System	28 Aug 2020 03:32:07
User entered '27 Aug 2020 22:32'	System	28 Aug 2020 03:32:07



US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 4'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:35', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f5a910ed-3446-4e63-8237-3a773e91ff7e'	System	29 Aug 2020 03:28:50
User entered 'Does not interfere with activity (2)'	System	29 Aug 2020 03:28:50

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:38', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f5a910ed-3446-4e63-8237-3a773e91ff7e'	System	29 Aug 2020 03:28:50
User entered 'No (N)'	System	29 Aug 2020 03:28:50

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:41', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f5a910ed-3446-4e63-8237-3a773e91ff7e'	System	29 Aug 2020 03:28:50
User entered 'No (N)'	System	29 Aug 2020 03:28:50

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:44', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f5a910ed-3446-4e63-8237-3a773e91ff7e'	System	29 Aug 2020 03:28:50
User entered 'None (1)'	System	29 Aug 2020 03:28:50

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f5a910ed-3446-4e63-8237-3a773e91ff7e'	System	29 Aug 2020 03:28:50
User entered '28 Aug 2020 22:28'	System	29 Aug 2020 03:28:50



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 5'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:49', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '5dac4487-f508-400c-bb63-40fd275ad9e1'	System	30 Aug 2020 00:47:05
User entered 'None (1)'	System	30 Aug 2020 00:47:05

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:52', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '5dac4487-f508-400c-bb63-40fd275ad9e1'	System	30 Aug 2020 00:47:05
User entered 'No (N)'	System	30 Aug 2020 00:47:05

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:54', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '5dac4487-f508-400c-bb63-40fd275ad9e1'	System	30 Aug 2020 00:47:05
User entered 'No (N)'	System	30 Aug 2020 00:47:05

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:57', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '5dac4487-f508-400c-bb63-40fd275ad9e1'	System	30 Aug 2020 00:47:05
User entered 'None (1)'	System	30 Aug 2020 00:47:05

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:46:59', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '5dac4487-f508-400c-bb63-40fd275ad9e1'	System	30 Aug 2020 00:47:05
User entered '29 Aug 2020 19:46'	System	30 Aug 2020 00:47:05



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 6'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:43', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b0ae3826-f384-462a-bb6e-5fdf0dc15b46'	System	31 Aug 2020 02:32:58
User entered 'None (1)'	System	31 Aug 2020 02:32:58

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b0ae3826-f384-462a-bb6e-5fdf0dc15b46'	System	31 Aug 2020 02:32:58
User entered 'No (N)'	System	31 Aug 2020 02:32:58

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:49', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b0ae3826-f384-462a-bb6e-5fdf0dc15b46'	System	31 Aug 2020 02:32:58
User entered 'No (N)'	System	31 Aug 2020 02:32:58

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:53', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b0ae3826-f384-462a-bb6e-5fdf0dc15b46'	System	31 Aug 2020 02:32:58
User entered 'None (1)'	System	31 Aug 2020 02:32:58

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:55', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b0ae3826-f384-462a-bb6e-5fdf0dc15b46'	System	31 Aug 2020 02:32:58
User entered '30 Aug 2020 21:32'	System	31 Aug 2020 02:32:58



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 7'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '3cdf6b4-9ee9-41c8-a80f-a4eb4b1d7b10'	System	01 Sep 2020 04:43:16
User entered 'None (1)'	System	01 Sep 2020 04:43:16

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:05', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '3cdfc6b4-9ee9-41c8-a80f-a4eb4b1d7b10'	System	01 Sep 2020 04:43:16
User entered 'No (N)'	System	01 Sep 2020 04:43:16

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:07', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '3cdf6b4-9ee9-41c8-a80f-a4eb4b1d7b10'	System	01 Sep 2020 04:43:16
User entered 'No (N)'	System	01 Sep 2020 04:43:16

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:09', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '3cdf6b4-9ee9-41c8-a80f-a4eb4b1d7b10'	System	01 Sep 2020 04:43:16
User entered 'None (1)'	System	01 Sep 2020 04:43:16

US3292304

Folder: Diary Dose 1 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '3cdf6b4-9ee9-41c8-a80f-a4eb4b1d7b10'	System	01 Sep 2020 04:43:16
User entered '31 Aug 2020 23:43'	System	01 Sep 2020 04:43:16



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:50', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4b13f11-a397-41e5-96cb-a8b525611eaa'	System	25 Aug 2020 19:28:30
User entered 'None (0)'	System	25 Aug 2020 19:28:30

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:27:55', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4b13f11-a397-41e5-96cb-a8b525611eaa'	System	25 Aug 2020 19:28:30
User entered 'None (0)'	System	25 Aug 2020 19:28:30

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:28:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4b13f11-a397-41e5-96cb-a8b525611eaa'	System	25 Aug 2020 19:28:30
User entered 'None (0)'	System	25 Aug 2020 19:28:30

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:28:05', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4b13f11-a397-41e5-96cb-a8b525611eaa'	System	25 Aug 2020 19:28:30
User entered 'None (0)'	System	25 Aug 2020 19:28:30

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:28:09', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4b13f11-a397-41e5-96cb-a8b525611eaa'	System	25 Aug 2020 19:28:30
User entered 'None (0)'	System	25 Aug 2020 19:28:30



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:28:14', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4b13f11-a397-41e5-96cb-a8b525611eaa'	System	25 Aug 2020 19:28:30
User entered 'None (0)'	System	25 Aug 2020 19:28:30

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:28:22', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4b13f11-a397-41e5-96cb-a8b525611eaa'	System	25 Aug 2020 19:28:30
User entered 'No (N)'	System	25 Aug 2020 19:28:30

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T14:28:24', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4b13f11-a397-41e5-96cb-a8b525611eaa'	System	25 Aug 2020 19:28:30
User entered '25 Aug 2020 14:28'	System	25 Aug 2020 19:28:30

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 14:02'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 16:32'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:25', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b8dbeac7-98c8-447d-adec-560be2016217'	System	26 Aug 2020 03:33:07
User entered 'None (0)'	System	26 Aug 2020 03:33:07

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:29', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b8dbeac7-98c8-447d-adec-560be2016217'	System	26 Aug 2020 03:33:07
User entered 'None (0)'	System	26 Aug 2020 03:33:07



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:39', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b8dbeac7-98c8-447d-adec-560be2016217'	System	26 Aug 2020 03:33:07
User entered 'None (0)'	System	26 Aug 2020 03:33:07

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:42', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b8dbeac7-98c8-447d-adec-560be2016217'	System	26 Aug 2020 03:33:07
User entered 'None (0)'	System	26 Aug 2020 03:33:07

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:46', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b8dbeac7-98c8-447d-adec-560be2016217'	System	26 Aug 2020 03:33:07
User entered 'None (0)'	System	26 Aug 2020 03:33:07

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:48', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b8dbeac7-98c8-447d-adec-560be2016217'	System	26 Aug 2020 03:33:07
User entered 'None (0)'	System	26 Aug 2020 03:33:07

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:32:59', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b8dbeac7-98c8-447d-adec-560be2016217'	System	26 Aug 2020 03:33:07
User entered 'No (N)'	System	26 Aug 2020 03:33:07

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-25T22:33:01', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b8dbeac7-98c8-447d-adec-560be2016217'	System	26 Aug 2020 03:33:07
User entered '25 Aug 2020 22:33'	System	26 Aug 2020 03:33:07

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Aug 2020 17:27'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 19:26:39



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 2'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:25', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9c4161df-5f7a-42a0-bbb5-096ca32d9566'	System	27 Aug 2020 03:26:53
User entered 'None (0)'	System	27 Aug 2020 03:26:53

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:29', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9c4161df-5f7a-42a0-bbb5-096ca32d9566'	System	27 Aug 2020 03:26:53
User entered 'None (0)'	System	27 Aug 2020 03:26:53

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:32', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9c4161df-5f7a-42a0-bbb5-096ca32d9566'	System	27 Aug 2020 03:26:53
User entered 'None (0)'	System	27 Aug 2020 03:26:53

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:39', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9c4161df-5f7a-42a0-bbb5-096ca32d9566'	System	27 Aug 2020 03:26:53
User entered 'None (0)'	System	27 Aug 2020 03:26:53

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:41', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9c4161df-5f7a-42a0-bbb5-096ca32d9566'	System	27 Aug 2020 03:26:53
User entered 'None (0)'	System	27 Aug 2020 03:26:53

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:43', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9c4161df-5f7a-42a0-bbb5-096ca32d9566'	System	27 Aug 2020 03:26:53
User entered 'None (0)'	System	27 Aug 2020 03:26:53

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:48', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9c4161df-5f7a-42a0-bbb5-096ca32d9566'	System	27 Aug 2020 03:26:53
User entered 'No (N)'	System	27 Aug 2020 03:26:53



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-26T22:26:50', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9c4161df-5f7a-42a0-bbb5-096ca32d9566'	System	27 Aug 2020 03:26:53
User entered '26 Aug 2020 22:26'	System	27 Aug 2020 03:26:53

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 3'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:08', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'cf093978-f9e4-4852-9c99-f73486769848'	System	28 Aug 2020 03:32:26
User entered 'None (0)'	System	28 Aug 2020 03:32:26

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:10', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'cf093978-f9e4-4852-9c99-f73486769848'	System	28 Aug 2020 03:32:26
User entered 'None (0)'	System	28 Aug 2020 03:32:26

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'cf093978-f9e4-4852-9c99-f73486769848'	System	28 Aug 2020 03:32:26
User entered 'None (0)'	System	28 Aug 2020 03:32:26

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:14', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'cf093978-f9e4-4852-9c99-f73486769848'	System	28 Aug 2020 03:32:26
User entered 'None (0)'	System	28 Aug 2020 03:32:26



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:15', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'cf093978-f9e4-4852-9c99-f73486769848'	System	28 Aug 2020 03:32:26
User entered 'None (0)'	System	28 Aug 2020 03:32:26

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:17', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'cf093978-f9e4-4852-9c99-f73486769848'	System	28 Aug 2020 03:32:26
User entered 'None (0)'	System	28 Aug 2020 03:32:26

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:20', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'cf093978-f9e4-4852-9c99-f73486769848'	System	28 Aug 2020 03:32:26
User entered 'No (N)'	System	28 Aug 2020 03:32:26

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-27T22:32:22', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'cf093978-f9e4-4852-9c99-f73486769848'	System	28 Aug 2020 03:32:26
User entered '27 Aug 2020 22:32'	System	28 Aug 2020 03:32:26

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 4'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:51', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b4d2e80b-d659-46e3-9aa9-cb79a5c8e91f'	System	29 Aug 2020 03:29:14
User entered 'None (0)'	System	29 Aug 2020 03:29:14



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:54', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b4d2e80b-d659-46e3-9aa9-cb79a5c8e91f'	System	29 Aug 2020 03:29:14
User entered 'None (0)'	System	29 Aug 2020 03:29:14

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:28:57', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b4d2e80b-d659-46e3-9aa9-cb79a5c8e91f'	System	29 Aug 2020 03:29:14
User entered 'None (0)'	System	29 Aug 2020 03:29:14

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:29:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b4d2e80b-d659-46e3-9aa9-cb79a5c8e91f'	System	29 Aug 2020 03:29:14
User entered 'None (0)'	System	29 Aug 2020 03:29:14

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:29:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b4d2e80b-d659-46e3-9aa9-cb79a5c8e91f'	System	29 Aug 2020 03:29:14
User entered 'None (0)'	System	29 Aug 2020 03:29:14

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:29:04', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b4d2e80b-d659-46e3-9aa9-cb79a5c8e91f'	System	29 Aug 2020 03:29:14
User entered 'None (0)'	System	29 Aug 2020 03:29:14

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:29:08', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b4d2e80b-d659-46e3-9aa9-cb79a5c8e91f'	System	29 Aug 2020 03:29:14
User entered 'No (N)'	System	29 Aug 2020 03:29:14

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-28T22:29:11', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b4d2e80b-d659-46e3-9aa9-cb79a5c8e91f'	System	29 Aug 2020 03:29:14
User entered '28 Aug 2020 22:29'	System	29 Aug 2020 03:29:14

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 19:26:39



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 5'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:47:03', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f88fa93a-e82e-4835-a7f8-d8842ccd0ced'	System	30 Aug 2020 00:47:35
User entered 'None (0)'	System	30 Aug 2020 00:47:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:47:06', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f88fa93a-e82e-4835-a7f8-d8842ccd0ced'	System	30 Aug 2020 00:47:35
User entered 'None (0)'	System	30 Aug 2020 00:47:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:47:08', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f88fa93a-e82e-4835-a7f8-d8842ccd0ced'	System	30 Aug 2020 00:47:35
User entered 'None (0)'	System	30 Aug 2020 00:47:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:47:10', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f88fa93a-e82e-4835-a7f8-d8842ccd0ced'	System	30 Aug 2020 00:47:35
User entered 'None (0)'	System	30 Aug 2020 00:47:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:47:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f88fa93a-e82e-4835-a7f8-d8842ccd0ced'	System	30 Aug 2020 00:47:35
User entered 'None (0)'	System	30 Aug 2020 00:47:35

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:47:14', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f88fa93a-e82e-4835-a7f8-d8842ccd0ced'	System	30 Aug 2020 00:47:35
User entered 'None (0)'	System	30 Aug 2020 00:47:35



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:47:28', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f88fa93a-e82e-4835-a7f8-d8842ccd0ced'	System	30 Aug 2020 00:47:35
User entered 'No (N)'	System	30 Aug 2020 00:47:35

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-29T19:47:30', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f88fa93a-e82e-4835-a7f8-d8842ccd0ced'	System	30 Aug 2020 00:47:35
User entered '29 Aug 2020 19:47'	System	30 Aug 2020 00:47:35

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 6'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:32:58', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c9c4349a-f095-4591-9c2e-8c683e71a104'	System	31 Aug 2020 02:33:16
User entered 'None (0)'	System	31 Aug 2020 02:33:16

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:33:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c9c4349a-f095-4591-9c2e-8c683e71a104'	System	31 Aug 2020 02:33:16
User entered 'None (0)'	System	31 Aug 2020 02:33:16

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:33:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c9c4349a-f095-4591-9c2e-8c683e71a104'	System	31 Aug 2020 02:33:16
User entered 'None (0)'	System	31 Aug 2020 02:33:16



US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:33:03', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c9c4349a-f095-4591-9c2e-8c683e71a104'	System	31 Aug 2020 02:33:16
User entered 'None (0)'	System	31 Aug 2020 02:33:16

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:33:05', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c9c4349a-f095-4591-9c2e-8c683e71a104'	System	31 Aug 2020 02:33:16
User entered 'None (0)'	System	31 Aug 2020 02:33:16

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:33:06', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c9c4349a-f095-4591-9c2e-8c683e71a104'	System	31 Aug 2020 02:33:16
User entered 'None (0)'	System	31 Aug 2020 02:33:16

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:33:10', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c9c4349a-f095-4591-9c2e-8c683e71a104'	System	31 Aug 2020 02:33:16
User entered 'No (N)'	System	31 Aug 2020 02:33:16

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-30T21:33:13', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c9c4349a-f095-4591-9c2e-8c683e71a104'	System	31 Aug 2020 02:33:16
User entered '30 Aug 2020 21:33'	System	31 Aug 2020 02:33:16

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 7'	System	25 Aug 2020 19:26:39



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:16', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2fd40b6c-687b-4f57-aa99-0bfb58d11f90'	System	01 Sep 2020 04:43:35
User entered 'None (0)'	System	01 Sep 2020 04:43:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:17', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2fd40b6c-687b-4f57-aa99-0bfb58d11f90'	System	01 Sep 2020 04:43:35
User entered 'None (0)'	System	01 Sep 2020 04:43:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:19', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2fd40b6c-687b-4f57-aa99-0bfb58d11f90'	System	01 Sep 2020 04:43:35
User entered 'None (0)'	System	01 Sep 2020 04:43:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:21', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2fd40b6c-687b-4f57-aa99-0bfb58d11f90'	System	01 Sep 2020 04:43:35
User entered 'None (0)'	System	01 Sep 2020 04:43:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:22', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2fd40b6c-687b-4f57-aa99-0bfb58d11f90'	System	01 Sep 2020 04:43:35
User entered 'None (0)'	System	01 Sep 2020 04:43:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:24', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2fd40b6c-687b-4f57-aa99-0bfb58d11f90'	System	01 Sep 2020 04:43:35
User entered 'None (0)'	System	01 Sep 2020 04:43:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:28', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2fd40b6c-687b-4f57-aa99-0bfb58d11f90'	System	01 Sep 2020 04:43:35
User entered 'No (N)'	System	01 Sep 2020 04:43:35

US3292304

Folder: Diary Dose 1 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-08-31T23:43:30', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2fd40b6c-687b-4f57-aa99-0bfb58d11f90'	System	01 Sep 2020 04:43:35
User entered '31 Aug 2020 23:43'	System	01 Sep 2020 04:43:35



**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Diary Dose 1 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:11:52
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	02 Sep 2020 18:31:45

US3292304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
DataPoint Verified.		01 Mar 2021 22:07:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Nov 2020 15:28:34
User entered '02 Sep 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 15:28:34
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:11:52
User entered '2 Sep 2020'	Kristy Trevino (b) (4)	02 Sep 2020 18:31:45
	(b) (4)	

**US3292304**

**Folder: Safety Call Day 8 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:11:52
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	02 Sep 2020 18:31:45

US3292304

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:11:52
User entered empty.	Kristy Trevino (b) (4)	02 Sep 2020 18:31:45

US3292304

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:11:58
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	02 Sep 2020 18:31:51

**US3292304**

**Folder: Safety Call Day 8 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'l'	System	02 Sep 2020 18:31:51



**US3292304**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:23
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	09 Sep 2020 23:27:16

US3292304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
DataPoint Verified.		01 Mar 2021 22:08:10
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Un-verified.	(b) (4)	
	Antonio Gutierrez (b) (4)	10 Nov 2020 15:29:26
User entered '09 Sep 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	10 Nov 2020 15:29:26
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:23
User entered '9 Sep 2020'	Kristy Trevino (b) (4)	09 Sep 2020 23:27:16
	(b) (4)	

**US3292304**

**Folder: Safety Call Day 15 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:23
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	09 Sep 2020 23:27:16

US3292304

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:23
User entered empty.	Kristy Trevino (b) (4)	09 Sep 2020 23:27:16

US3292304

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:32
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	09 Sep 2020 23:27:23

**US3292304**

**Folder: Safety Call Day 15 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 Apr 2021 19:36:55
User entered 'l'	System	09 Sep 2020 23:27:23

**US3292304**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[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)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:52
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	16 Sep 2020 19:59:23

**US3292304**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

**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)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:52
User entered '16 Sep 2020'	Kristy Trevino (b) (4)	16 Sep 2020 19:59:23



**US3292304**

**Folder: Safety Call Day 22 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[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)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:52
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	16 Sep 2020 19:59:23

US3292304

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[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)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:52
User entered empty.	Kristy Trevino (b) (4)	16 Sep 2020 19:59:23

US3292304

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:09

[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)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:12:57
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	16 Sep 2020 19:59:28

**US3292304**

**Folder: Safety Call Day 22 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 09:13:27
User entered 'I'	System	16 Sep 2020 19:59:28

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:20:27
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Sep 2020 18:04:07

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:20:29
User entered '22 Sep 2020'	Gerardo Pena (b) (4)	22 Sep 2020 18:04:07

US3292304

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:09

[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 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:20:29
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4)	22 Sep 2020 18:04:07

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'VISIT2'	System	22 Sep 2020 18:04:07



US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:12
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:26
User entered '22 Sep 2020'	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:31
User entered '10:49'	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered '22 Sep 2020 10:49'	System	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:33
User entered '36.4' C	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:40
User entered 'Oral (Oral)'	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.		09 Mar 2021 16:38:11
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 18:06:17



**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:41
User entered '78'	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'bpm'	System	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:45
User entered '16'	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'breaths/min'	System	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:49
User entered '114'	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'mmHg'	System	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:37:52
User entered '76'	Gerardo Pena (b) (4)	22 Sep 2020 18:06:17

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:30:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'mmHg'	System	22 Sep 2020 18:06:17



US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:48:10
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:48:13
User entered '22 Sep 2020'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:48:47
User entered '12:22'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered '22 Sep 2020 12:22'	System	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:48:49
User entered '36.9' C	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:48:52
User entered 'Oral (Oral)'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:30:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:48:53
User entered empty.	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02



**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:49:03
User entered '63'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'bpm'	System	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:49:07
User entered '16'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'breaths/min'	System	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:49:09
User entered '114'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'mmHg'	System	22 Sep 2020 18:15:02

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Vital Signs - Dosing (2)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:49:12
User entered '78'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:02

US3292304

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:30:09

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'mmHg'	System	22 Sep 2020 18:15:02



**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:30:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:49:26
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:29

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:30:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:49:44
User entered '22 Sep 2020'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:29

US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:50:37
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	22 Sep 2020 17:02:59

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:30:09**

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:50:46
User entered empty.	Nathan Cortez (b) (4)	22 Sep 2020 17:02:59

US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

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 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:50:48
User entered empty.	Nathan Cortez (b) (4)	22 Sep 2020 17:02:59

US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 17:02:59

US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:50:51
User entered '22 Sep 2020'	Nathan Cortez (b) (4)	22 Sep 2020 17:02:59

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Exposure**

**Generated On: 09 Jun 2021 16:30:09**

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:50:55
User entered '11:51'	Nathan Cortez (b) (4)	22 Sep 2020 17:02:59



US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered '22 Sep 2020 11:51'	System	22 Sep 2020 17:02:59

US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 20:50:58
User entered 'Left Arm (LEFT ARM)'	Nathan Cortez (b) (4)	22 Sep 2020 17:02:59

US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.		01 Oct 2020 20:51:04
User entered 'ONCE'	System	22 Sep 2020 17:02:59

US3292304

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:30:09

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:51:39
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:48

US3292304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:51:44
User entered '22 Sep 2020'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:48

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:52:37
User entered '11:01'	Gerardo Pena (b) (4)	22 Sep 2020 18:15:48

US3292304

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:09

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered '22 Sep 2020 11:01'	System	22 Sep 2020 18:15:48



US3292304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:30:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.		16 Apr 2021 17:58:59
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '22 Sep 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 18:16:33

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 18:16:33

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:52:53
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Sep 2020 18:16:33

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:30:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:52:55
User entered '11:04'	Gerardo Pena (b) (4)	22 Sep 2020 18:16:33

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered '22 Sep 2020 11:04'	System	22 Sep 2020 18:16:33

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 18:16:33

US3292304

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:30:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.		16 Apr 2021 17:58:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 18:16:33

**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:30:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.	(b) (4)	16 Apr 2021 17:58:54
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 18:16:33



**US3292304**

**Folder: Visit 2 Day 29 (1)**

**Form: Central Laboratory - Nasopharyngeal Swab (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered empty.	System	22 Sep 2020 18:16:33

US3292304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 20:53:06
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Sep 2020 18:16:39

US3292304

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:09

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'I'	System	22 Sep 2020 18:16:39

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:23:51', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b591b8ed-585d-49fa-8b1f-adeefeba5008'	System	22 Sep 2020 17:24:09
User entered 'Yes (Y)'	System	22 Sep 2020 17:24:09

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:23:57', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b591b8ed-585d-49fa-8b1f-adeefeba5008'	System	22 Sep 2020 17:24:09
User entered '98.2'	System	22 Sep 2020 17:24:09

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:01', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b591b8ed-585d-49fa-8b1f-adeefeba5008'	System	22 Sep 2020 17:24:09
User entered 'No (N)'	System	22 Sep 2020 17:24:09

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:04', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b591b8ed-585d-49fa-8b1f-adeefeba5008'	System	22 Sep 2020 17:24:09
User entered '22 Sep 2020 12:24'	System	22 Sep 2020 17:24:09



**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 12:11'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 14:41'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T22:54:20', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '337f9e8f-d635-4011-a8b4-d0c1602536c4'	System	23 Sep 2020 04:28:19
User entered 'Yes (Y)'	System	23 Sep 2020 04:28:19

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:28:08', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '337f9e8f-d635-4011-a8b4-d0c1602536c4'	System	23 Sep 2020 04:28:19
User entered '98.8'	System	23 Sep 2020 04:28:19

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:28:11', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '337f9e8f-d635-4011-a8b4-d0c1602536c4'	System	23 Sep 2020 04:28:19
User entered 'No (N)'	System	23 Sep 2020 04:28:19

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:28:14', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '337f9e8f-d635-4011-a8b4-d0c1602536c4'	System	23 Sep 2020 04:28:19
User entered '22 Sep 2020 23:28'	System	23 Sep 2020 04:28:19

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 15:36'	System	22 Sep 2020 17:02:59



US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 2'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:11:55', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'aa0f4938-e08c-4252-8066-b3557f0fc59f'	System	23 Sep 2020 20:12:18
User entered 'Yes (Y)'	System	23 Sep 2020 20:12:18

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'aa0f4938-e08c-4252-8066-b3557f0fc59f'	System	23 Sep 2020 20:12:18
User entered '100.8'	System	23 Sep 2020 20:12:18

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:04', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'aa0f4938-e08c-4252-8066-b3557f0fc59f'	System	23 Sep 2020 20:12:18
User entered 'Yes (Y)'	System	23 Sep 2020 20:12:18

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will ask patient at D36 phone call' (Site from System).	(b) (4), (b) (6)	29 Sep 2020 11:51:42
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'will ask patient at D36 phone call' (Site from System).	Dawn Killian (b) (4)	24 Sep 2020 01:31:25
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	23 Sep 2020 20:12:18
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ec346cfbe)', Time: '2020-09-23T15:12:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'aa0f4938-e08c-4252-8066-b3557f0fc59f'	System	23 Sep 2020 20:12:18
User entered '1'	System	23 Sep 2020 20:12:18

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'aa0f4938-e08c-4252-8066-b3557f0fc59f'	System	23 Sep 2020 20:12:18
User entered '0'	System	23 Sep 2020 20:12:18

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:14', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'aa0f4938-e08c-4252-8066-b3557f0fc59f'	System	23 Sep 2020 20:12:18
User entered '23 Sep 2020 15:12'	System	23 Sep 2020 20:12:18



**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(2)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 3'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:05:42', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd639fa70-436f-4dac-b669-ed41f8b2a6c6'	System	25 Sep 2020 04:06:00
User entered 'Yes (Y)'	System	25 Sep 2020 04:06:00

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:05:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd639fa70-436f-4dac-b669-ed41f8b2a6c6'	System	25 Sep 2020 04:06:00
User entered '98.1'	System	25 Sep 2020 04:06:00

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:05:53', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd639fa70-436f-4dac-b669-ed41f8b2a6c6'	System	25 Sep 2020 04:06:00
User entered 'No (N)'	System	25 Sep 2020 04:06:00

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:05:56', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd639fa70-436f-4dac-b669-ed41f8b2a6c6'	System	25 Sep 2020 04:06:00
User entered '24 Sep 2020 23:05'	System	25 Sep 2020 04:06:00

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:02:59



**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 4'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:00:33', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd67ed0e4-0b8c-412b-a0e6-637eabbac849'	System	26 Sep 2020 04:00:55
User entered 'Yes (Y)'	System	26 Sep 2020 04:00:55

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:00:38', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd67ed0e4-0b8c-412b-a0e6-637eabbac849'	System	26 Sep 2020 04:00:55
User entered '98.1'	System	26 Sep 2020 04:00:55

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:00:45', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd67ed0e4-0b8c-412b-a0e6-637eabbac849'	System	26 Sep 2020 04:00:55
User entered 'No (N)'	System	26 Sep 2020 04:00:55

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:00:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd67ed0e4-0b8c-412b-a0e6-637eabbac849'	System	26 Sep 2020 04:00:55
User entered '25 Sep 2020 23:00'	System	26 Sep 2020 04:00:55

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:02:59



US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 5'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:29:33', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '43ec7085-f2d5-4046-9f83-c183d4e2668c'	System	27 Sep 2020 00:29:41
User entered 'No (N)'	System	27 Sep 2020 00:29:41

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:29:36', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '43ec7085-f2d5-4046-9f83-c183d4e2668c'	System	27 Sep 2020 00:29:41
User entered 'No (N)'	System	27 Sep 2020 00:29:41

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:29:39', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '43ec7085-f2d5-4046-9f83-c183d4e2668c'	System	27 Sep 2020 00:29:41
User entered '26 Sep 2020 19:29'	System	27 Sep 2020 00:29:41

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(5)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 6'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-27T23:59:49', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '431462e5-7e0c-4f91-844f-c1f35d06d2f7'	System	28 Sep 2020 05:00:08
User entered 'Yes (Y)'	System	28 Sep 2020 05:00:08



US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-27T23:59:55', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '431462e5-7e0c-4f91-844f-c1f35d06d2f7'	System	28 Sep 2020 05:00:08
User entered '97.7'	System	28 Sep 2020 05:00:08

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-27T23:59:56', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '431462e5-7e0c-4f91-844f-c1f35d06d2f7'	System	28 Sep 2020 05:00:08
User entered 'No (N)'	System	28 Sep 2020 05:00:08

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(6)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-27T23:59:59', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '431462e5-7e0c-4f91-844f-c1f35d06d2f7'	System	28 Sep 2020 05:00:08
User entered '27 Sep 2020 23:59'	System	28 Sep 2020 05:00:08

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Temperature\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 7'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '107ff49e-b127-4fe5-87f8-dcc3b86df777'	System	29 Sep 2020 15:39:08
User entered 'No (N)'	System	29 Sep 2020 15:39:08

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '107ff49e-b127-4fe5-87f8-dcc3b86df777'	System	29 Sep 2020 15:39:08
User entered 'No (N)'	System	29 Sep 2020 15:39:08



US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:05', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '107ff49e-b127-4fe5-87f8-dcc3b86df777'	System	29 Sep 2020 15:39:08
User entered '29 Sep 2020 10:39'	System	29 Sep 2020 15:39:08

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Temperature\_Day(7)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:09', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '82d4dec7-3656-4553-8374-d2c5e93d9c00'	System	22 Sep 2020 17:24:26
User entered 'None (1)'	System	22 Sep 2020 17:24:26

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:13', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '82d4dec7-3656-4553-8374-d2c5e93d9c00'	System	22 Sep 2020 17:24:26
User entered 'No (N)'	System	22 Sep 2020 17:24:26

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:18', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '82d4dec7-3656-4553-8374-d2c5e93d9c00'	System	22 Sep 2020 17:24:26
User entered 'No (N)'	System	22 Sep 2020 17:24:26

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:21', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '82d4dec7-3656-4553-8374-d2c5e93d9c00'	System	22 Sep 2020 17:24:26
User entered 'None (1)'	System	22 Sep 2020 17:24:26



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:23', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '82d4dec7-3656-4553-8374-d2c5e93d9c00'	System	22 Sep 2020 17:24:26
User entered '22 Sep 2020 12:24'	System	22 Sep 2020 17:24:26

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 12:11'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 14:41'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:28:19', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0c5a009f-5436-43eb-9d48-be474dbfb1d6'	System	23 Sep 2020 04:30:50
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 04:30:50

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:29:53', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0c5a009f-5436-43eb-9d48-be474dbfb1d6'	System	23 Sep 2020 04:30:50
User entered 'Yes (Y)'	System	23 Sep 2020 04:30:50

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

Please record - **REDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site redness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:30:26', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0c5a009f-5436-43eb-9d48-be474dbfb1d6'	System	23 Sep 2020 04:30:50
User entered '2'	System	23 Sep 2020 04:30:50

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:30:33', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0c5a009f-5436-43eb-9d48-be474dbfb1d6'	System	23 Sep 2020 04:30:50
User entered 'No (N)'	System	23 Sep 2020 04:30:50



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:30:41', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0c5a009f-5436-43eb-9d48-be474dbfb1d6'	System	23 Sep 2020 04:30:50
User entered 'None (1)'	System	23 Sep 2020 04:30:50

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:30:45', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0c5a009f-5436-43eb-9d48-be474dbfb1d6'	System	23 Sep 2020 04:30:50
User entered '22 Sep 2020 23:30'	System	23 Sep 2020 04:30:50

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 15:36'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 2'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:22', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '935020d4-aeca-45b3-a8bb-532fba9d0dc2'	System	23 Sep 2020 20:12:42
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 20:12:42

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:25', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '935020d4-aeca-45b3-a8bb-532fba9d0dc2'	System	23 Sep 2020 20:12:42
User entered 'No (N)'	System	23 Sep 2020 20:12:42

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:28', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '935020d4-aeca-45b3-a8bb-532fba9d0dc2'	System	23 Sep 2020 20:12:42
User entered 'No (N)'	System	23 Sep 2020 20:12:42



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:36', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '935020d4-aeca-45b3-a8bb-532fba9d0dc2'	System	23 Sep 2020 20:12:42
User entered 'None (1)'	System	23 Sep 2020 20:12:42

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:12:38', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '935020d4-aeca-45b3-a8bb-532fba9d0dc2'	System	23 Sep 2020 20:12:42
User entered '23 Sep 2020 15:12'	System	23 Sep 2020 20:12:42

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(2)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 3'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:03', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9bf2c101-295b-4a5c-8ae6-bd373c7f3f83'	System	25 Sep 2020 04:06:29
User entered 'Does not interfere with activity (2)'	System	25 Sep 2020 04:06:29

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9bf2c101-295b-4a5c-8ae6-bd373c7f3f83'	System	25 Sep 2020 04:06:29
User entered 'No (N)'	System	25 Sep 2020 04:06:29

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:14', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9bf2c101-295b-4a5c-8ae6-bd373c7f3f83'	System	25 Sep 2020 04:06:29
User entered 'No (N)'	System	25 Sep 2020 04:06:29



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:20', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9bf2c101-295b-4a5c-8ae6-bd373c7f3f83'	System	25 Sep 2020 04:06:29
User entered 'None (1)'	System	25 Sep 2020 04:06:29

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:23', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '9bf2c101-295b-4a5c-8ae6-bd373c7f3f83'	System	25 Sep 2020 04:06:29
User entered '24 Sep 2020 23:06'	System	25 Sep 2020 04:06:29

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(3)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 4'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '860b0a22-bf6d-4cac-a4cc-bd9c4c1f227a'	System	26 Sep 2020 04:01:38
User entered 'Does not interfere with activity (2)'	System	26 Sep 2020 04:01:38

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '860b0a22-bf6d-4cac-a4cc-bd9c4c1f227a'	System	26 Sep 2020 04:01:38
User entered 'No (N)'	System	26 Sep 2020 04:01:38

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:05', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '860b0a22-bf6d-4cac-a4cc-bd9c4c1f227a'	System	26 Sep 2020 04:01:38
User entered 'No (N)'	System	26 Sep 2020 04:01:38



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:08', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '860b0a22-bf6d-4cac-a4cc-bd9c4c1f227a'	System	26 Sep 2020 04:01:38
User entered 'None (1)'	System	26 Sep 2020 04:01:38

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:09', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '860b0a22-bf6d-4cac-a4cc-bd9c4c1f227a'	System	26 Sep 2020 04:01:38
User entered '25 Sep 2020 23:01'	System	26 Sep 2020 04:01:38

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(4)

Generated On: 09 Jun 2021 16:30:09

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 5'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:29:44', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8d494d58-2d09-437a-823d-ac7fb4a2d3da'	System	27 Sep 2020 00:30:02
User entered 'Does not interfere with activity (2)'	System	27 Sep 2020 00:30:02

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:29:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8d494d58-2d09-437a-823d-ac7fb4a2d3da'	System	27 Sep 2020 00:30:02
User entered 'No (N)'	System	27 Sep 2020 00:30:02

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:29:51', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8d494d58-2d09-437a-823d-ac7fb4a2d3da'	System	27 Sep 2020 00:30:02
User entered 'No (N)'	System	27 Sep 2020 00:30:02



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:29:54', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8d494d58-2d09-437a-823d-ac7fb4a2d3da'	System	27 Sep 2020 00:30:02
User entered 'None (1)'	System	27 Sep 2020 00:30:02

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(5)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:29:56', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8d494d58-2d09-437a-823d-ac7fb4a2d3da'	System	27 Sep 2020 00:30:02
User entered '26 Sep 2020 19:29'	System	27 Sep 2020 00:30:02

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 6'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:01', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f90aeff6-7cbe-484e-94aa-7a030ac58dfa'	System	28 Sep 2020 05:00:09
User entered 'None (1)'	System	28 Sep 2020 05:00:09

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:03', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f90aeff6-7cbe-484e-94aa-7a030ac58dfa'	System	28 Sep 2020 05:00:09
User entered 'No (N)'	System	28 Sep 2020 05:00:09

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:04', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f90aeff6-7cbe-484e-94aa-7a030ac58dfa'	System	28 Sep 2020 05:00:09
User entered 'No (N)'	System	28 Sep 2020 05:00:09



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:06', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f90aeff6-7cbe-484e-94aa-7a030ac58dfa'	System	28 Sep 2020 05:00:09
User entered 'None (1)'	System	28 Sep 2020 05:00:09

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(6)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:07', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f90aeff6-7cbe-484e-94aa-7a030ac58dfa'	System	28 Sep 2020 05:00:09
User entered '28 Sep 2020 00:00'	System	28 Sep 2020 05:00:09

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 7'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:10', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '149f87de-3727-4ace-847f-a39e57d8d72d'	System	29 Sep 2020 15:39:26
User entered 'None (1)'	System	29 Sep 2020 15:39:26

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:13', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '149f87de-3727-4ace-847f-a39e57d8d72d'	System	29 Sep 2020 15:39:26
User entered 'No (N)'	System	29 Sep 2020 15:39:26

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:15', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '149f87de-3727-4ace-847f-a39e57d8d72d'	System	29 Sep 2020 15:39:26
User entered 'No (N)'	System	29 Sep 2020 15:39:26



US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:18', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '149f87de-3727-4ace-847f-a39e57d8d72d'	System	29 Sep 2020 15:39:26
User entered 'None (1)'	System	29 Sep 2020 15:39:26

US3292304

Folder: Diary Dose 2 (1)

Form: Injection Site\_Day(7)

Generated On: 09 Jun 2021 16:30:09

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:21', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '149f87de-3727-4ace-847f-a39e57d8d72d'	System	29 Sep 2020 15:39:26
User entered '29 Sep 2020 10:39'	System	29 Sep 2020 15:39:26

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: Injection Site\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:26', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e66acb53-9134-4567-9b4c-539099adcc53'	System	22 Sep 2020 17:24:48
User entered 'None (0)'	System	22 Sep 2020 17:24:48

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:28', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e66acb53-9134-4567-9b4c-539099adcc53'	System	22 Sep 2020 17:24:48
User entered 'None (0)'	System	22 Sep 2020 17:24:48

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:31', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e66acb53-9134-4567-9b4c-539099adcc53'	System	22 Sep 2020 17:24:48
User entered 'None (0)'	System	22 Sep 2020 17:24:48



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:33', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e66acb53-9134-4567-9b4c-539099adcc53'	System	22 Sep 2020 17:24:48
User entered 'None (0)'	System	22 Sep 2020 17:24:48

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:34', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e66acb53-9134-4567-9b4c-539099adcc53'	System	22 Sep 2020 17:24:48
User entered 'None (0)'	System	22 Sep 2020 17:24:48

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:36', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e66acb53-9134-4567-9b4c-539099adcc53'	System	22 Sep 2020 17:24:48
User entered 'None (0)'	System	22 Sep 2020 17:24:48

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:42', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e66acb53-9134-4567-9b4c-539099adcc53'	System	22 Sep 2020 17:24:48
User entered 'No (N)'	System	22 Sep 2020 17:24:48

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/1)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T12:24:44', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e66acb53-9134-4567-9b4c-539099adcc53'	System	22 Sep 2020 17:24:48
User entered '22 Sep 2020 12:24'	System	22 Sep 2020 17:24:48

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 12:11'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/1)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 14:41'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 17:02:59



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ec346cfbe)', Time: '2020-09-22T23:30:48', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7d07f0b0-8e72-4adc-aea3-11aec2fb09b6'	System	23 Sep 2020 04:31:05
User entered 'None (0)'	System	23 Sep 2020 04:31:05

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ec346cfbe)', Time: '2020-09-22T23:30:50', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7d07f0b0-8e72-4adc-aea3-11aec2fb09b6'	System	23 Sep 2020 04:31:05
User entered 'None (0)'	System	23 Sep 2020 04:31:05

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ec346cfbe)', Time: '2020-09-22T23:30:51', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7d07f0b0-8e72-4adc-aea3-11aec2fb09b6'	System	23 Sep 2020 04:31:05
User entered 'None (0)'	System	23 Sep 2020 04:31:05

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ec346cfbe)', Time: '2020-09-22T23:30:53', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7d07f0b0-8e72-4adc-aea3-11aec2fb09b6'	System	23 Sep 2020 04:31:05
User entered 'None (0)'	System	23 Sep 2020 04:31:05

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:30:54', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7d07f0b0-8e72-4adc-aea3-11aec2fb09b6'	System	23 Sep 2020 04:31:05
User entered 'None (0)'	System	23 Sep 2020 04:31:05

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ec346cfbe)', Time: '2020-09-22T23:30:55', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7d07f0b0-8e72-4adc-aea3-11aec2fb09b6'	System	23 Sep 2020 04:31:05
User entered 'None (0)'	System	23 Sep 2020 04:31:05

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ec346cfbe)', Time: '2020-09-22T23:30:58', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7d07f0b0-8e72-4adc-aea3-11aec2fb09b6'	System	23 Sep 2020 04:31:05
User entered 'No (N)'	System	23 Sep 2020 04:31:05

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-22T23:31:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '7d07f0b0-8e72-4adc-aea3-11aec2fb09b6'	System	23 Sep 2020 04:31:05
User entered '22 Sep 2020 23:31'	System	23 Sep 2020 04:31:05



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(1/2)

Generated On: 09 Jun 2021 16:30:09

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '22 Sep 2020 15:36'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(1/2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 2'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:13:21', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '90ac6d3a-b50d-45c1-a0af-15bb7cfb5eda'	System	23 Sep 2020 20:14:04
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity (2)'	System	23 Sep 2020 20:14:04

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:13:20', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '90ac6d3a-b50d-45c1-a0af-15bb7cfb5eda'	System	23 Sep 2020 20:14:04
User entered 'No interference with activity (1)'	System	23 Sep 2020 20:14:04

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:13:30', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '90ac6d3a-b50d-45c1-a0af-15bb7cfb5eda'	System	23 Sep 2020 20:14:04
User entered 'Some interference with activity (2)'	System	23 Sep 2020 20:14:04

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:13:34', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '90ac6d3a-b50d-45c1-a0af-15bb7cfb5eda'	System	23 Sep 2020 20:14:04
User entered 'None (0)'	System	23 Sep 2020 20:14:04

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:13:37', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '90ac6d3a-b50d-45c1-a0af-15bb7cfb5eda'	System	23 Sep 2020 20:14:04
User entered 'None (0)'	System	23 Sep 2020 20:14:04



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:13:40', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '90ac6d3a-b50d-45c1-a0af-15bb7cfb5eda'	System	23 Sep 2020 20:14:04
User entered 'Some interference with activity not requiring medical attention (2)'	System	23 Sep 2020 20:14:04

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:13:48', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '90ac6d3a-b50d-45c1-a0af-15bb7cfb5eda'	System	23 Sep 2020 20:14:04
User entered 'No (N)'	System	23 Sep 2020 20:14:04

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(2)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-23T15:13:57', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '90ac6d3a-b50d-45c1-a0af-15bb7cfb5eda'	System	23 Sep 2020 20:14:04
User entered '23 Sep 2020 15:13'	System	23 Sep 2020 20:14:04

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(2)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 3'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:31', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8ab0131a-c1ad-46ed-8b43-4599da74fa1c'	System	25 Sep 2020 04:06:50
User entered 'None (0)'	System	25 Sep 2020 04:06:50

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:33', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8ab0131a-c1ad-46ed-8b43-4599da74fa1c'	System	25 Sep 2020 04:06:50
User entered 'None (0)'	System	25 Sep 2020 04:06:50



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:36', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8ab0131a-c1ad-46ed-8b43-4599da74fa1c'	System	25 Sep 2020 04:06:50
User entered 'None (0)'	System	25 Sep 2020 04:06:50

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:38', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8ab0131a-c1ad-46ed-8b43-4599da74fa1c'	System	25 Sep 2020 04:06:50
User entered 'None (0)'	System	25 Sep 2020 04:06:50

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:40', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8ab0131a-c1ad-46ed-8b43-4599da74fa1c'	System	25 Sep 2020 04:06:50
User entered 'None (0)'	System	25 Sep 2020 04:06:50

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:42', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8ab0131a-c1ad-46ed-8b43-4599da74fa1c'	System	25 Sep 2020 04:06:50
User entered 'None (0)'	System	25 Sep 2020 04:06:50

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:45', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8ab0131a-c1ad-46ed-8b43-4599da74fa1c'	System	25 Sep 2020 04:06:50
User entered 'No (N)'	System	25 Sep 2020 04:06:50

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(3)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-24T23:06:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '8ab0131a-c1ad-46ed-8b43-4599da74fa1c'	System	25 Sep 2020 04:06:50
User entered '24 Sep 2020 23:06'	System	25 Sep 2020 04:06:50

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(3)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 17:02:59



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 4'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:15', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2da67246-9bc3-48f8-9b35-d4315dd1293a'	System	26 Sep 2020 04:02:15
User entered 'No interference with activity (1)'	System	26 Sep 2020 04:02:15

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:17', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2da67246-9bc3-48f8-9b35-d4315dd1293a'	System	26 Sep 2020 04:02:15
User entered 'None (0)'	System	26 Sep 2020 04:02:15

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:18', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2da67246-9bc3-48f8-9b35-d4315dd1293a'	System	26 Sep 2020 04:02:15
User entered 'None (0)'	System	26 Sep 2020 04:02:15

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:20', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2da67246-9bc3-48f8-9b35-d4315dd1293a'	System	26 Sep 2020 04:02:15
User entered 'None (0)'	System	26 Sep 2020 04:02:15

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:21', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2da67246-9bc3-48f8-9b35-d4315dd1293a'	System	26 Sep 2020 04:02:15
User entered 'None (0)'	System	26 Sep 2020 04:02:15

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:23', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2da67246-9bc3-48f8-9b35-d4315dd1293a'	System	26 Sep 2020 04:02:15
User entered 'None (0)'	System	26 Sep 2020 04:02:15

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(4)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:26', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2da67246-9bc3-48f8-9b35-d4315dd1293a'	System	26 Sep 2020 04:02:15
User entered 'No (N)'	System	26 Sep 2020 04:02:15



**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-25T23:01:28', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2da67246-9bc3-48f8-9b35-d4315dd1293a'	System	26 Sep 2020 04:02:15
User entered '25 Sep 2020 23:01'	System	26 Sep 2020 04:02:15

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(4)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 5'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:30:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'fb2df319-563e-4741-87e6-f51f959fbfff'	System	27 Sep 2020 00:30:24
User entered 'None (0)'	System	27 Sep 2020 00:30:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:30:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'fb2df319-563e-4741-87e6-f51f959fbfff'	System	27 Sep 2020 00:30:24
User entered 'None (0)'	System	27 Sep 2020 00:30:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:30:04', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'fb2df319-563e-4741-87e6-f51f959fbfff'	System	27 Sep 2020 00:30:24
User entered 'None (0)'	System	27 Sep 2020 00:30:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:30:05', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'fb2df319-563e-4741-87e6-f51f959fbfff'	System	27 Sep 2020 00:30:24
User entered 'None (0)'	System	27 Sep 2020 00:30:24



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:30:07', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'fb2df319-563e-4741-87e6-f51f959fbfff'	System	27 Sep 2020 00:30:24
User entered 'None (0)'	System	27 Sep 2020 00:30:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:30:10', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'fb2df319-563e-4741-87e6-f51f959fbfff'	System	27 Sep 2020 00:30:24
User entered 'None (0)'	System	27 Sep 2020 00:30:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:30:16', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'fb2df319-563e-4741-87e6-f51f959fbfff'	System	27 Sep 2020 00:30:24
User entered 'No (N)'	System	27 Sep 2020 00:30:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(5)

Generated On: 09 Jun 2021 16:30:09

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-26T19:30:19', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'fb2df319-563e-4741-87e6-f51f959fbfff'	System	27 Sep 2020 00:30:24
User entered '26 Sep 2020 19:30'	System	27 Sep 2020 00:30:24

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(5)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 6'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:10', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b99c7738-d260-488e-93b6-cba6bd372e1b'	System	28 Sep 2020 05:00:24
User entered 'None (0)'	System	28 Sep 2020 05:00:24



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:11', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b99c7738-d260-488e-93b6-cba6bd372e1b'	System	28 Sep 2020 05:00:24
User entered 'None (0)'	System	28 Sep 2020 05:00:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b99c7738-d260-488e-93b6-cba6bd372e1b'	System	28 Sep 2020 05:00:24
User entered 'None (0)'	System	28 Sep 2020 05:00:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:13', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b99c7738-d260-488e-93b6-cba6bd372e1b'	System	28 Sep 2020 05:00:24
User entered 'None (0)'	System	28 Sep 2020 05:00:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:14', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b99c7738-d260-488e-93b6-cba6bd372e1b'	System	28 Sep 2020 05:00:24
User entered 'None (0)'	System	28 Sep 2020 05:00:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:15', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b99c7738-d260-488e-93b6-cba6bd372e1b'	System	28 Sep 2020 05:00:24
User entered 'None (0)'	System	28 Sep 2020 05:00:24

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(6)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:18', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b99c7738-d260-488e-93b6-cba6bd372e1b'	System	28 Sep 2020 05:00:24
User entered 'No (N)'	System	28 Sep 2020 05:00:24

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-28T00:00:20', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b99c7738-d260-488e-93b6-cba6bd372e1b'	System	28 Sep 2020 05:00:24
User entered '28 Sep 2020 00:00'	System	28 Sep 2020 05:00:24

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 17:02:59



**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(6)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	22 Sep 2020 17:02:59
User entered 'Day 7'	System	22 Sep 2020 17:02:59

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:26', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6b31b8dc-25b7-4d05-8684-afb608043a99'	System	29 Sep 2020 15:40:41
User entered 'None (0)'	System	29 Sep 2020 15:40:41

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**FATIGUE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:32', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6b31b8dc-25b7-4d05-8684-afb608043a99'	System	29 Sep 2020 15:40:41
User entered 'None (0)'	System	29 Sep 2020 15:40:41

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:36', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6b31b8dc-25b7-4d05-8684-afb608043a99'	System	29 Sep 2020 15:40:41
User entered 'None (0)'	System	29 Sep 2020 15:40:41

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:39', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6b31b8dc-25b7-4d05-8684-afb608043a99'	System	29 Sep 2020 15:40:41
User entered 'None (0)'	System	29 Sep 2020 15:40:41

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:42', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6b31b8dc-25b7-4d05-8684-afb608043a99'	System	29 Sep 2020 15:40:41
User entered 'None (0)'	System	29 Sep 2020 15:40:41

US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

**CHILLS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:45', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6b31b8dc-25b7-4d05-8684-afb608043a99'	System	29 Sep 2020 15:40:41
User entered 'None (0)'	System	29 Sep 2020 15:40:41



US3292304

Folder: Diary Dose 2 (1)

Form: General\_Day(7)

Generated On: 09 Jun 2021 16:30:09

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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:39:55', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6b31b8dc-25b7-4d05-8684-afb608043a99'	System	29 Sep 2020 15:40:41
User entered 'No (N)'	System	29 Sep 2020 15:40:41

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-09-29T10:40:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '6b31b8dc-25b7-4d05-8684-afb608043a99'	System	29 Sep 2020 15:40:41
User entered '29 Sep 2020 10:40'	System	29 Sep 2020 15:40:41

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Diary Dose 2 (1)**

**Form: General\_Day(7)**

**Generated On: 09 Jun 2021 16:30:09**

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 17:02:59

**US3292304**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	28 Jan 2021 15:15:55
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:19:23

**US3292304**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:15:55
User entered '1 Oct 2020'		01 Oct 2020 21:19:23

**US3292304**

**Folder: Safety Call Day 36 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	28 Jan 2021 15:15:55
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4), (b) (6)	01 Oct 2020 21:19:23

US3292304

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:15:55
User entered 'Attempted to contact patient 3x no answer, unable to lvm due to mailbox not being set up.'		01 Oct 2020 21:19:23



**US3292304**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	28 Jan 2021 15:15:59
User entered 'Yes (Y)'	(b) (4), (b) (6)	01 Oct 2020 21:19:28

**US3292304**

**Folder: Safety Call Day 36 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'l'	System	01 Oct 2020 21:19:28

**US3292304**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:17:52
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	07 Oct 2020 16:13:38

**US3292304**

**Folder: Safety Call Day 43 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:17:52
User entered '7 Oct 2020'	Kristy Trevino (b) (4)	07 Oct 2020 16:13:38

US3292304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:17:52
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4)	07 Oct 2020 16:13:38

US3292304

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:17:52
User entered empty.	Kristy Trevino (b) (4)	07 Oct 2020 16:13:38

**US3292304**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:18:01
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	07 Oct 2020 16:15:12

**US3292304**

**Folder: Safety Call Day 43 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'l'	System	07 Oct 2020 16:15:12



US3292304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:18:26
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 21:31:24
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 21:31:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 21:31:24
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 21:30:43
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 21:30:43
User entered 'Yes (Y)'		15 Oct 2020 21:27:00

US3292304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	28 Jan 2021 15:18:26
User entered '15 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 21:31:24
User entered empty; reason for change Data Entry Error		15 Oct 2020 21:30:43
User entered '15 Oct 2020'		15 Oct 2020 21:27:00

US3292304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	28 Jan 2021 15:18:26
User entered 'Contact Not Made (CONTACT NOT MADE)' reason for change: Data Entry Error		15 Oct 2020 21:31:24
User entered empty; reason for change Data Entry Error		15 Oct 2020 21:30:43
User entered 'Contact Made (CONTACT MADE)'		15 Oct 2020 21:27:00

US3292304

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:18:26
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	15 Oct 2020 21:32:52
User entered 'Contacted subject 3x w/ sms sent.' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 21:32:52
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided. Please review and reconcile.' (Site from System).	System	15 Oct 2020 21:31:24
User entered empty.	(b) (4), (b) (6)	15 Oct 2020 21:27:00

US3292304

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:18:55
User closed query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 21:29:29
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	15 Oct 2020 21:29:29
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 21:29:29
User opened query 'Data is required. Please complete.' (Site from System).	System	15 Oct 2020 21:27:20
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	15 Oct 2020 21:27:20
User entered 'Yes (Y)'		15 Oct 2020 21:27:04

**US3292304**

**Folder: Safety Call Day 50 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'l'	System	15 Oct 2020 21:29:29
User entered empty.	System	15 Oct 2020 21:27:20
User entered 'l'	System	15 Oct 2020 21:27:04

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:23:48
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	30 Oct 2020 21:38:41

US3292304

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:30:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	28 Jan 2021 15:23:48
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4), (b) (6)	11 Nov 2020 09:34:59
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' answered with 'date is correct' (Site from System).	Gerardo Pena (b) (4)	30 Oct 2020 21:39:12
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4)	30 Oct 2020 21:38:41
User entered '30 Oct 2020'	System	30 Oct 2020 21:38:41
	Gerardo Pena (b) (4)	30 Oct 2020 21:38:41
	(b) (4)	



**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[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 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:23:48
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4)	30 Oct 2020 21:38:41

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'VISIT3'	System	30 Oct 2020 21:38:41

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered '30 Oct 2020'	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered '12:44'	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered '30 Oct 2020 12:44'	System	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered '36.3' C	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered 'Oral (Oral)'	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30



**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered empty.	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered '96'	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'bpm'	System	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered '12'	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30

US3292304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'breaths/min'	System	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered '128'	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'mmHg'	System	30 Oct 2020 21:46:30

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:25:50
User entered '87'	Gerardo Pena (b) (4)	30 Oct 2020 21:46:30



**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'mmHg'	System	30 Oct 2020 21:46:30

US3292304

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:30:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Jan 2021 15:26:10
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	30 Oct 2020 21:52:58

US3292304

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:30:09

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:26:10
User entered empty.	Kevin Martinez (b) (4)	30 Oct 2020 21:52:58

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:26:25
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	30 Oct 2020 21:53:19

US3292304

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:26:25
User entered '30 Oct 2020'	Kevin Martinez (b) (4)	30 Oct 2020 21:53:19

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:26:25
User entered '12:57'	Kevin Martinez (b) (4)	30 Oct 2020 21:53:19



**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered '30 Oct 2020 12:57'	System	30 Oct 2020 21:53:19

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	28 Jan 2021 15:26:31
User entered 'Yes (Y)'	Kevin Martinez (b) (4)	30 Oct 2020 21:53:02

**US3292304**

**Folder: Visit 3 Day 57 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'I'	System	30 Oct 2020 21:53:02

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 64'	System	25 Aug 2020 19:26:39

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

[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)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

Have you been exposed to someone with 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)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52
Data entry locked.	System	25 Aug 2020 19:26:39
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 17:26:52
Data entry locked.	System	25 Aug 2020 19:26:39
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 19:26:39

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 71'	System	25 Aug 2020 19:26:39



US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

[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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-11-01T08:38:48', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'a1c9c134-6454-452c-8096-ba7784b966a8'	System	01 Nov 2020 14:39:05
User entered 'Yes (Y)'	System	01 Nov 2020 14:39:05

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

Have you been exposed to someone with 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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-11-01T08:38:42', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'a1c9c134-6454-452c-8096-ba7784b966a8'	System	01 Nov 2020 14:39:05
User entered 'No (N)'	System	01 Nov 2020 14:39:05

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-11-01T08:38:40', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'a1c9c134-6454-452c-8096-ba7784b966a8'	System	01 Nov 2020 14:39:05
User entered 'No (N)'	System	01 Nov 2020 14:39:05

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-11-01T08:38:37', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'a1c9c134-6454-452c-8096-ba7784b966a8'	System	01 Nov 2020 14:39:05
User entered 'No (N)'	System	01 Nov 2020 14:39:05

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-11-01T08:38:58', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'a1c9c134-6454-452c-8096-ba7784b966a8'	System	01 Nov 2020 14:39:05
User entered '01 Nov 2020 08:38:58'	System	01 Nov 2020 14:39:05

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered 'Day 78'	System	25 Aug 2020 19:26:39



US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

[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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-11-08T10:51:40', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '44513ba3-592f-42c4-8887-e73347ac6075'	System	08 Nov 2020 16:51:50
User entered 'No (N)'	System	08 Nov 2020 16:51:50

US3292304

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:30:09

Have you been exposed to someone with 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 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-11-08T10:51:44', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '44513ba3-592f-42c4-8887-e73347ac6075'	System	08 Nov 2020 16:51:50
User entered 'No (N)'	System	08 Nov 2020 16:51:50

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-11-08T10:51:46', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '44513ba3-592f-42c4-8887-e73347ac6075'	System	08 Nov 2020 16:51:50
User entered '08 Nov 2020 10:51:46'	System	08 Nov 2020 16:51:50

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:12:58
Data entry locked.	System	25 Aug 2020 19:26:39
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 19:26:39

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2020-12-03T21:43:25', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd4f44935-cb91-4bd3-aa9c-003370996295'	System	04 Dec 2020 03:43:50
User entered 'No (N)'	System	04 Dec 2020 03:43:50

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2020-12-03T21:43:30', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd4f44935-cb91-4bd3-aa9c-003370996295'	System	04 Dec 2020 03:43:50
User entered 'No (N)'	System	04 Dec 2020 03:43:50

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-12-03T21:43:33', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'd4f44935-cb91-4bd3-aa9c-003370996295'	System	04 Dec 2020 03:43:50
User entered '03 Dec 2020 21:43:33'	System	04 Dec 2020 03:43:50

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2020-12-10T01:17:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '54d74213-7c34-41e3-b8a2-31c1ea542830'	System	10 Dec 2020 07:17:58
User entered 'No (N)'	System	10 Dec 2020 07:17:58

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2020-12-10T01:17:52', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '54d74213-7c34-41e3-b8a2-31c1ea542830'	System	10 Dec 2020 07:17:58
User entered 'No (N)'	System	10 Dec 2020 07:17:58

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-12-10T01:17:55', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '54d74213-7c34-41e3-b8a2-31c1ea542830'	System	10 Dec 2020 07:17:58
User entered '10 Dec 2020 01:17:55'	System	10 Dec 2020 07:17:58

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2020-12-17T00:25:31', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2398e0d5-5916-46c8-9812-5113350ae379'	System	17 Dec 2020 06:25:47
User entered 'No (N)'	System	17 Dec 2020 06:25:47

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2020-12-17T00:25:40', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2398e0d5-5916-46c8-9812-5113350ae379'	System	17 Dec 2020 06:25:47
User entered 'No (N)'	System	17 Dec 2020 06:25:47

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-12-17T00:25:44', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2398e0d5-5916-46c8-9812-5113350ae379'	System	17 Dec 2020 06:25:47
User entered '17 Dec 2020 00:25:44'	System	17 Dec 2020 06:25:47

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2020-12-27T12:48:18', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c198ebb3-ef6e-4973-8b8c-59a1f1619acc'	System	27 Dec 2020 18:48:34
User entered 'No (N)'	System	27 Dec 2020 18:48:34

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2020-12-27T12:48:29', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c198ebb3-ef6e-4973-8b8c-59a1f1619acc'	System	27 Dec 2020 18:48:34
User entered 'No (N)'	System	27 Dec 2020 18:48:34



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-12-27T12:48:32', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c198ebb3-ef6e-4973-8b8c-59a1f1619acc'	System	27 Dec 2020 18:48:34
User entered '27 Dec 2020 12:48:32'	System	27 Dec 2020 18:48:34

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2020-12-31T00:03:04', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e33963bf-1504-4f6f-87f3-2c5befc4c8c2'	System	31 Dec 2020 06:03:14
User entered 'No (N)'	System	31 Dec 2020 06:03:14

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2020-12-31T00:03:09', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e33963bf-1504-4f6f-87f3-2c5befc4c8c2'	System	31 Dec 2020 06:03:14
User entered 'No (N)'	System	31 Dec 2020 06:03:14

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2020-12-31T00:03:12', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'e33963bf-1504-4f6f-87f3-2c5bfc4c8c2'	System	31 Dec 2020 06:03:14
User entered '31 Dec 2020 00:03:12'	System	31 Dec 2020 06:03:14

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-01-07T00:02:44', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1d84e4eb-5c56-4d4b-a77d-b41ec0b0807c'	System	07 Jan 2021 06:02:50
User entered 'No (N)'	System	07 Jan 2021 06:02:50

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-01-07T00:02:46', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1d84e4eb-5c56-4d4b-a77d-b41ec0b0807c'	System	07 Jan 2021 06:02:50
User entered 'No (N)'	System	07 Jan 2021 06:02:50

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-01-07T00:02:49', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1d84e4eb-5c56-4d4b-a77d-b41ec0b0807c'	System	07 Jan 2021 06:02:50
User entered '07 Jan 2021 00:02:49'	System	07 Jan 2021 06:02:50

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-01-14T00:06:53', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '66740764-3fee-4315-8c86-4f2576ab591b'	System	14 Jan 2021 06:07:06
User entered 'No (N)'	System	14 Jan 2021 06:07:06

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-01-14T00:06:56', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '66740764-3fee-4315-8c86-4f2576ab591b'	System	14 Jan 2021 06:07:06
User entered 'No (N)'	System	14 Jan 2021 06:07:06

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-01-14T00:06:59', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '66740764-3fee-4315-8c86-4f2576ab591b' User entered '14 Jan 2021 00:06:59'	System	14 Jan 2021 06:07:06
	System	14 Jan 2021 06:07:06

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-01-21T00:44:23', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c0a4b779-90fe-4c6f-af8e-187e406963c0'	System	21 Jan 2021 06:45:14
User entered 'Yes (Y)'	System	21 Jan 2021 06:45:14

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-01-21T00:44:38', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c0a4b779-90fe-4c6f-af8e-187e406963c0'	System	21 Jan 2021 06:45:14
User entered 'No (N)'	System	21 Jan 2021 06:45:14



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-01-21T00:44:45', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c0a4b779-90fe-4c6f-af8e-187e406963c0'	System	21 Jan 2021 06:45:14
User entered 'No (N)'	System	21 Jan 2021 06:45:14

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-01-21T00:44:56', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c0a4b779-90fe-4c6f-af8e-187e406963c0'	System	21 Jan 2021 06:45:14
User entered 'Yes (Y)'	System	21 Jan 2021 06:45:14

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-01-21T00:45:02', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c0a4b779-90fe-4c6f-af8e-187e406963c0'	System	21 Jan 2021 06:45:14
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	21 Jan 2021 06:45:14

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-01-21T00:45:06', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'c0a4b779-90fe-4c6f-af8e-187e406963c0'	System	21 Jan 2021 06:45:14
User entered '21 Jan 2021 00:45:06'	System	21 Jan 2021 06:45:14

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-01-28T00:12:06', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2e8164d5-3015-4645-a128-4fbf8796f28d'	System	28 Jan 2021 06:12:23
User entered 'No (N)'	System	28 Jan 2021 06:12:23



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-01-28T00:12:19', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2e8164d5-3015-4645-a128-4fbf8796f28d'	System	28 Jan 2021 06:12:23
User entered 'No (N)'	System	28 Jan 2021 06:12:23

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-01-28T00:12:21', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2e8164d5-3015-4645-a128-4fbf8796f28d'	System	28 Jan 2021 06:12:23
User entered '28 Jan 2021 00:12:21'	System	28 Jan 2021 06:12:23

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-02-04T00:01:37', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1d2906bb-f43d-44d8-9b37-77655baff92c'	System	04 Feb 2021 06:01:52
User entered 'No (N)'	System	04 Feb 2021 06:01:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-02-04T00:01:41', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1d2906bb-f43d-44d8-9b37-77655baff92c'	System	04 Feb 2021 06:01:52
User entered 'No (N)'	System	04 Feb 2021 06:01:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-02-04T00:01:47', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '1d2906bb-f43d-44d8-9b37-77655baff92c'	System	04 Feb 2021 06:01:52
User entered '04 Feb 2021 00:01:47'	System	04 Feb 2021 06:01:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-02-11T09:29:25', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'db1a8cf0-42a2-4f21-b60f-a53fc68ae7f5'	System	11 Feb 2021 15:29:37
User entered 'No (N)'	System	11 Feb 2021 15:29:37

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-02-11T09:29:29', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'db1a8cf0-42a2-4f21-b60f-a53fc68ae7f5'	System	11 Feb 2021 15:29:37
User entered 'No (N)'	System	11 Feb 2021 15:29:37

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-02-11T09:29:32', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'db1a8cf0-42a2-4f21-b60f-a53fc68ae7f5'	System	11 Feb 2021 15:29:37
User entered '11 Feb 2021 09:29:32'	System	11 Feb 2021 15:29:37

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-02-18T00:03:43', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f611534d-a285-4afe-b17a-f0ee4f980287'	System	18 Feb 2021 06:03:51
User entered 'No (N)'	System	18 Feb 2021 06:03:51

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-02-18T00:03:46', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f611534d-a285-4afe-b17a-f0ee4f980287'	System	18 Feb 2021 06:03:51
User entered 'No (N)'	System	18 Feb 2021 06:03:51

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-02-18T00:03:48', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f611534d-a285-4afe-b17a-f0ee4f980287'	System	18 Feb 2021 06:03:51
User entered '18 Feb 2021 00:03:48'	System	18 Feb 2021 06:03:51

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-02-25T00:01:33-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2ebd004a-7d0e-4f16-9e33-c017b22b2f0e' User entered 'Yes (Y)'	System	25 Feb 2021 06:02:13



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-02-25T00:01:39-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2ebd004a-7d0e-4f16-9e33-c017b22b2f0e' User entered 'No (N)'	System	25 Feb 2021 06:02:13

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-02-25T00:01:44-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2ebd004a-7d0e-4f16-9e33-c017b22b2f0e' User entered 'No (N)'	System	25 Feb 2021 06:02:13

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-02-25T00:02:00-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2ebd004a-7d0e-4f16-9e33-c017b22b2f0e' User entered 'No (N)'	System	25 Feb 2021 06:02:13

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-02-25T00:02:02-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2ebd004a-7d0e-4f16-9e33-c017b22b2f0e' User entered '25 Feb 2021 00:02:02'	System	25 Feb 2021 06:02:13
	System	25 Feb 2021 06:02:13

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-03-04T00:23:19-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '47118857-87f9-43ec-9120-6e97242308ea' User entered 'No (N)'	System	04 Mar 2021 06:23:29



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-03-04T00:23:23-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '47118857-87f9-43ec-9120-6e97242308ea'	System	04 Mar 2021 06:23:29
User entered 'No (N)'	System	04 Mar 2021 06:23:29

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-03-04T00:23:25-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '47118857-87f9-43ec-9120-6e97242308ea' User entered '04 Mar 2021 00:23:25'	System	04 Mar 2021 06:23:29
	System	04 Mar 2021 06:23:29

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-03-11T00:01:21-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b04f53ec-05bf-4014-89ca-c17f76e38f6b'	System	11 Mar 2021 06:01:29
User entered 'No (N)'	System	11 Mar 2021 06:01:29

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-03-11T00:01:24-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b04f53ec-05bf-4014-89ca-c17f76e38f6b'	System	11 Mar 2021 06:01:29
User entered 'No (N)'	System	11 Mar 2021 06:01:29

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-03-11T00:01:26-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'b04f53ec-05bf-4014-89ca-c17f76e38f6b' User entered '11 Mar 2021 00:01:26'	System	11 Mar 2021 06:01:29
	System	11 Mar 2021 06:01:29



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-03-18T00:01:17-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'eec582f1-68ef-48e5-a43e-3a21b5fd79a5'	System	18 Mar 2021 05:01:28
User entered 'No (N)'	System	18 Mar 2021 05:01:28

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-03-18T00:01:22-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'eec582f1-68ef-48e5-a43e-3a21b5fd79a5'	System	18 Mar 2021 05:01:28
User entered 'No (N)'	System	18 Mar 2021 05:01:28

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-03-18T00:01:25-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'eec582f1-68ef-48e5-a43e-3a21b5fd79a5' User entered '18 Mar 2021 00:01:25'	System	18 Mar 2021 05:01:28
	System	18 Mar 2021 05:01:28

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-03-25T00:01:57-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0f9625e2-85b8-47e4-9e8b-d35ba1013ea6'	System	25 Mar 2021 05:02:07
User entered 'No (N)'	System	25 Mar 2021 05:02:07

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-03-25T00:01:59-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0f9625e2-85b8-47e4-9e8b-d35ba1013ea6'	System	25 Mar 2021 05:02:07
User entered 'No (N)'	System	25 Mar 2021 05:02:07

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-03-25T00:02:01-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '0f9625e2-85b8-47e4-9e8b-d35ba1013ea6'	System	25 Mar 2021 05:02:07
User entered '25 Mar 2021 00:02:01'	System	25 Mar 2021 05:02:07

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-04-01T00:01:34-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '38ecbbd6-782d-4a11-8ee8-aafe76879fcf' User entered 'No (N)'	System	01 Apr 2021 05:01:47



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-04-01T00:01:42-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '38ecbbd6-782d-4a11-8ee8-aafe76879fcf' User entered 'No (N)'	System	01 Apr 2021 05:01:47

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-04-01T00:01:44-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '38ecbbd6-782d-4a11-8ee8-aafe76879fcf' User entered '01 Apr 2021 00:01:44'	System	01 Apr 2021 05:01:47
	System	01 Apr 2021 05:01:47

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-04-08T00:01:45-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '86e0b93a-0df0-4430-a258-2fe81e303796'	System	08 Apr 2021 05:01:53
User entered 'No (N)'	System	08 Apr 2021 05:01:53

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-04-08T00:01:48-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '86e0b93a-0df0-4430-a258-2fe81e303796'	System	08 Apr 2021 05:01:53
User entered 'No (N)'	System	08 Apr 2021 05:01:53

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-04-08T00:01:50-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '86e0b93a-0df0-4430-a258-2fe81e303796'	System	08 Apr 2021 05:01:53
User entered '08 Apr 2021 00:01:50'	System	08 Apr 2021 05:01:53



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-04-15T00:19:11-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4bc90fb-cecf-4c25-9368-f479835d88e0' User entered 'Yes (Y)'	System	15 Apr 2021 05:19:32
	System	15 Apr 2021 05:19:32

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-04-15T00:19:13-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4bc90fb-cecf-4c25-9368-f479835d88e0' User entered 'No (N)'	System	15 Apr 2021 05:19:32

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-04-15T00:19:18-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4bc90fb-cecf-4c25-9368-f479835d88e0' User entered 'No (N)'	System	15 Apr 2021 05:19:32

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-04-15T00:19:22-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4bc90fb-cecf-4c25-9368-f479835d88e0' User entered 'No (N)'	System	15 Apr 2021 05:19:32
	System	15 Apr 2021 05:19:32

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-04-15T00:19:25-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: 'f4bc90fb-cecf-4c25-9368-f479835d88e0'	System	15 Apr 2021 05:19:32
User entered '15 Apr 2021 00:19:25'	System	15 Apr 2021 05:19:32



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-04-25T20:09:01-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2158d535-7ff3-4d6f-a7db-152fc6c2240c' User entered 'No (N)'	System	26 Apr 2021 01:11:46

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-04-25T20:09:04-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2158d535-7ff3-4d6f-a7db-152fc6c2240c' User entered 'No (N)'	System	26 Apr 2021 01:11:46

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-04-25T20:09:06-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '2158d535-7ff3-4d6f-a7db-152fc6c2240c'	System	26 Apr 2021 01:11:46
User entered '25 Apr 2021 20:09:06'	System	26 Apr 2021 01:11:46

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[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 (f974397ee346cfbe)', Time: '2021-04-29T00:01:16-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '61143d3c-5eb4-43e9-adaf-e68a79691b8d' User entered 'No (N)'	System	29 Apr 2021 05:01:38
	System	29 Apr 2021 05:01:38

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

Have you been exposed to someone with 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 (f974397ee346cfbe)', Time: '2021-04-29T00:01:18-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '61143d3c-5eb4-43e9-adaf-e68a79691b8d' User entered 'No (N)'	System	29 Apr 2021 05:01:38

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-04-29T00:01:21-05:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '61143d3c-5eb4-43e9-adaf-e68a79691b8d' User entered '29 Apr 2021 00:01:21'	System	29 Apr 2021 05:01:38
	System	29 Apr 2021 05:01:38

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:26:52



**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

**TIMEPOINT**

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:26:52

**US3292304**

**Folder: New Safety Follow Up Diary (1)**

**Form: Safety Follow Up Diary**

**Generated On: 09 Jun 2021 16:30:09**

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:26:52
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:26:52



US3292304

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:30:09**

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 09:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ec346cfbe)', Time: '2021-02-28T12:09:16-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '547ec914-ee1e-4ef2-a37e-f76e0a3902ee'	System	28 Feb 2021 18:12:25
User entered 'No (N)'	System	28 Feb 2021 18:12:25

**US3292304**

**Folder: Cosmetic Injections and Dermal Fillers**

**Form: Cosmetic Injection\_ Dermal Filler eDiary (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 09:38:12
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (f974397ee346cfbe)', Time: '2021-02-28T12:09:22-06:00', User OID: 'PatientReportedOutcome (US3292304)', ODM File OID: '547ec914-ee1e-4ef2-a37e-f76e0a3902ee' User entered '28 Feb 2021 12:09:22'	System	28 Feb 2021 18:12:25
	System	28 Feb 2021 18:12:25

**US3292304**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:46:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	20 Nov 2020 15:28:15

**US3292304**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:46:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '17 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	20 Nov 2020 15:28:15

**US3292304**

**Folder: Safety Call Day 85 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:46:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	20 Nov 2020 15:28:15

US3292304

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:30:09

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.	(b) (4)	09 Mar 2021 16:46:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	20 Nov 2020 15:28:15

**US3292304**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:46:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	20 Nov 2020 15:28:20

**US3292304**

**Folder: Safety Call Day 85 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 22:48:03
User entered 'l'	System	20 Nov 2020 15:28:20



**US3292304**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:48:33
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:07:17

**US3292304**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:48:33
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:07:17

**US3292304**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:48:33
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:07:17

**US3292304**

**Folder: Safety Call Day 119 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:48:33
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:07:17

**US3292304**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:49:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Dec 2020 17:07:23

**US3292304**

**Folder: Safety Call Day 119 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
User entered 'l'	System	23 Dec 2020 17:07:23

**US3292304**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:49:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Jan 2021 15:38:01

**US3292304**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:49:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '20 Jan 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Jan 2021 15:38:01



**US3292304**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:49:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Jan 2021 15:38:01

**US3292304**

**Folder: Safety Call Day 149 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:49:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Jan 2021 15:38:01

**US3292304**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:49:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Jan 2021 15:38:05

**US3292304**

**Folder: Safety Call Day 149 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
User entered 'l'	System	26 Jan 2021 15:38:05

**US3292304**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:52:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:29:06

**US3292304**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:52:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:29:06

**US3292304**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:52:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:29:06

**US3292304**

**Folder: Safety Call Day 179 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:52:21
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:29:06



**US3292304**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 16:53:47
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 00:29:12

**US3292304**

**Folder: Safety Call Day 179 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:49:57
User entered 'l'	System	20 Feb 2021 00:29:12

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:11
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Mar 2021 21:29:58

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:11
User entered '22 Mar 2021'	Gerardo Pena (b) (4)	22 Mar 2021 21:29:58

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[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 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:11
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4)	22 Mar 2021 21:29:58

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User entered 'VISIT4'	System	22 Mar 2021 21:29:58

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:30:17
User entered 'No (N)'		31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:30:17
User entered empty.		31 Mar 2021 19:28:39



**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:30:17
User entered empty.		31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User entered empty.	System	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	08 Apr 2021 16:30:17
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:17
User entered empty.		31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	08 Apr 2021 16:30:17
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:30:17
User entered empty.		31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User entered empty.	System	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:17
User entered empty.		31 Mar 2021 19:28:39



US3292304

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:30:09

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User entered empty.	System	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	08 Apr 2021 16:30:17
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User entered empty.	System	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	08 Apr 2021 16:30:17
User entered empty.	(b) (4), (b) (6)	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User entered empty.	System	31 Mar 2021 19:28:39

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Vital Signs**

**Generated On: 09 Jun 2021 16:30:09**

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:30:09**

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:30:22
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	22 Mar 2021 21:30:03



**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Physical Examination**

**Generated On: 09 Jun 2021 16:30:09**

**Date of examination (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:22
User entered empty.	Gerardo Pena (b) (4)	22 Mar 2021 21:30:03

US3292304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:09

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:54
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Mar 2021 21:30:25

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:52
User entered '22 Mar 2021'	Gerardo Pena (b) (4)	22 Mar 2021 21:30:25

US3292304

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:30:09

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User closed query 'Per source, collection time is 1254.' (Site from CRA).	(b) (4)	16 Apr 2021 17:57:06
DataPoint Verified.	(b) (4)	16 Apr 2021 17:57:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
Query 'Per source, collection time is 1254.' answered with 'updated' (Site from CRA).	(b) (4)	(b) (4)
User entered '12:54' reason for change: Data Entry Error	Dawn Killian (b) (4)	13 Apr 2021 19:27:36
User opened query 'Per source, collection time is 1254.' (Site from CRA).	(b) (4)	13 Apr 2021 19:27:32
User entered '09:50'	(b) (4), (b) (6)	08 Apr 2021 16:30:51
	Gerardo Pena (b) (4)	22 Mar 2021 21:30:25
	(b) (4)	

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User entered '22 Mar 2021 12:54'	System	13 Apr 2021 19:27:32
User entered '22 Mar 2021 09:50'	System	22 Mar 2021 21:30:25

US3292304

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 16:30:56
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	22 Mar 2021 21:30:29

**US3292304**

**Folder: Visit 4 Day 209 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 14:17:10
User entered 'I'	System	22 Mar 2021 21:30:29

**US3292304**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:38:20
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Apr 2021 15:23:09



**US3292304**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:38:20
User entered '20 Apr 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Apr 2021 15:23:09

**US3292304**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:38:20
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Apr 2021 15:23:09

**US3292304**

**Folder: Safety Call Day 239 (1)**

**Form: Safety Call**

**Generated On: 09 Jun 2021 16:30:09**

[Comments](#)

*If Contact Not Made, please provide Comments*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:38:20
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Apr 2021 15:23:09

US3292304

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:30:09

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:38:20
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	26 Apr 2021 15:23:12

**US3292304**

**Folder: Safety Call Day 239 (1)**

**Form: Continuing**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'l'	System	26 Apr 2021 15:23:12

US3292304

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

Form: Visit Date

Generated On: 09 Jun 2021 16:30:09

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
DataPoint Verified.	(b) (4)	09 Mar 2021 17:04:22
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:28

US3292304

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

Form: Visit Date

Generated On: 09 Jun 2021 16:30:09

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
DataPoint Verified.		09 Mar 2021 17:04:22
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered '2 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:28

**US3292304**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[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 10:44:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:04:22
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:28



**US3292304**

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

**Form: Visit Date**

**Generated On: 09 Jun 2021 16:30:09**

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
User entered 'UNBLND_DECIDE'	System	03 Mar 2021 17:55:28

US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
DataPoint Verified.		09 Mar 2021 17:04:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered '2 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:52

US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
DataPoint Verified.		30 Apr 2021 13:21:09
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:24
User entered '0'	(b) (4) Dawn Killian (b) (4)	23 Apr 2021 07:30:01
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:41:43

US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
DataPoint Verified.		09 Mar 2021 17:04:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:52

US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
DataPoint Verified.		30 Apr 2021 13:21:07
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
User closed query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).		26 Apr 2021 15:00:40
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:24
Query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	(b) (4) Dawn Killian (b) (4) (b) (4)	23 Apr 2021 07:30:08
User entered 'Amendment 6 or later (Amendment 6 or later)'	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 07:30:01
User opened query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	22 Apr 2021 04:51:36
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:41:43

US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
DataPoint Verified.		09 Mar 2021 17:04:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered '2 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:52

US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
DataPoint Verified.		09 Mar 2021 17:04:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:52

US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
DataPoint Verified.		09 Mar 2021 17:04:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:52



US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
DataPoint Verified.		09 Mar 2021 17:04:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:52

US3292304

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

Form: Unblinding

Generated On: 09 Jun 2021 16:30:09

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
DataPoint Verified.		09 Mar 2021 17:04:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:55:52

**US3292304**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:30:09**

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
User entered empty.	System	03 Mar 2021 17:55:52

**US3292304**

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

**Form: Unblinding**

**Generated On: 09 Jun 2021 16:30:09**

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 14:38:36
Data hard unlocked.		30 Apr 2021 06:42:47
Data hard locked.		29 Apr 2021 10:44:04
User entered empty.	System	03 Mar 2021 17:55:52

**US3292304**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:05:11
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:56:18

**US3292304**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

**Collection date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:05:11
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered '2 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:56:18

**US3292304**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:05:11
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered '11:22'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:56:18

**US3292304**

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

**Form: Immunogenicity Assessment**

**Generated On: 09 Jun 2021 16:30:09**

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
User entered '2 Mar 2021 11:22'	System	03 Mar 2021 17:56:18



**US3292304**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:30:09**

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:05:22
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:56:31

US3292304

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:30:09

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 11:23:28
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' answered with 'CRC to track with lab' (Site from DM).	Dawn Killian (b) (4) (b) (4)	13 Apr 2021 19:26:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:05:22
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 02MAR2021 is recorded under Participant Decision Visit / OL-D1 in EDC, however, the sample is missing in PPD Central lab. Please reconcile the data and amend Preclarus as appropriate or please ship the sample and provide both Accession number and the tracking details in the response. Thank you.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 07:34:48
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	05 Mar 2021 17:08:09
User entered '2 Mar 2021'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:56:31

**US3292304**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:30:09**

**Collection time (00:00 - 23:59)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
DataPoint Verified.	(b) (4)	09 Mar 2021 17:05:22
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 17:08:09
User entered '11:31'	(b) (4) Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 17:56:31

**US3292304**

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

**Form: Central Laboratory - Nasopharyngeal Swab (Single)**

**Generated On: 09 Jun 2021 16:30:09**

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 10:44:04
User entered '2 Mar 2021 11:31'	System	03 Mar 2021 17:56:31

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events Summary**

**Generated On: 09 Jun 2021 16:30:09**

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:51:03
User entered 'Yes (Y)'	Kristy Trevino (b) (4)	07 Oct 2020 16:48:55

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:41
Reviewed for Safety.		08 Oct 2020 12:02:50
User entered 'USA-US072-2020-mRNA-1273-P301000005'	System	08 Oct 2020 12:02:45
User entered 'New'	(b) (4), (b) (6)	08 Oct 2020 12:02:45

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:43
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal ulceration and perforation, HLT: Intestinal ulcers and perforation NEC, PT: Large intestine perforation, LLT: Perforated colon - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 17:21:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	07 Oct 2020 17:21:18
Data point term sent to Coder	System	07 Oct 2020 17:20:44
User entered 'PERFORATED COLON' reason for change: Data Entry Error	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:19:57
Data point term sent to Coder	System	07 Oct 2020 17:14:27
User entered 'Emergency Surgery due to perforated colon and a history of Diverticulosis'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:44
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:46
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:48
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:50
User entered '4 Oct 2020'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:52
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	07 Oct 2020 17:19:57
User entered empty; reason for change Data Entry Error	Kristy Trevino (b) (4)	07 Oct 2020 17:19:57
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	07 Oct 2020 17:14:16
User entered '09:00'	Kristy Trevino (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 17:19:57
User entered '4 Oct 2020 09:00'	System	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:54
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:56
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	07 Oct 2020 17:20:49
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	07 Oct 2020 17:20:49
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	07 Oct 2020 17:19:57
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	07 Oct 2020 17:19:57
User entered '6 Oct 2020' reason for change: Data Entry Error	Kristy Trevino (b) (4)	07 Oct 2020 17:19:57
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	07 Oct 2020 17:14:16
User entered empty.	Kristy Trevino (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:44:58
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	07 Oct 2020 17:19:57
User entered empty; reason for change Data Entry Error	Kristy Trevino (b) (4)	07 Oct 2020 17:19:57
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	07 Oct 2020 17:14:16
User entered '19:00'	Kristy Trevino (b) (4)	07 Oct 2020 17:14:16



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:01
User entered 'Grade 3/Severe (Grade 3/Severe)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:04
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:07
User entered '0'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:09
User entered '0'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System). DataPoint Verified.	(b) (4), (b) (6)	21 Nov 2020 10:03:20
		04 Nov 2020 22:45:11
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Pending Information' (Site from System).	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:21:04
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	07 Oct 2020 17:14:16
User entered 'I'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:15
User entered '04 Oct 2020' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	28 Oct 2020 19:37:30
User entered '6 Oct 2020'	(b) (4) Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 16:53:39
DataPoint Un-verified.		24 Nov 2020 23:35:39
User entered '16 Oct 2020' reason for change: New Information		24 Nov 2020 23:35:39
DataPoint Verified.		04 Nov 2020 22:45:17
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		29 Oct 2020 16:30:10
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Victoria Hernandez (b) (4)	28 Oct 2020 19:37:39
User entered '06 Oct 2020' reason for change: Data Entry Error	(b) (4)	28 Oct 2020 19:37:30
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:44:28
User entered empty.	Kristy Trevino (b) (4)	07 Oct 2020 17:14:16



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:19
User entered 'No (N)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:35
User entered empty.	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:37
User entered '0'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:40
User entered '0'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:42
User entered '0'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:47
User entered 'Not Related (NOT RELATED)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:49
User entered 'Not Related (NOT RELATED)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:45:55
User closed query 'PV Query: As the last dose of study drug was given on 22 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:30:14
Query 'PV Query: As the last dose of study drug was given on 22 Sep 2020, please update the action taken with study drug from none to not applicable.' answered with 'updated' (Site from Safety).	Victoria Hernandez (b) (4)	28 Oct 2020 19:37:45
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	28 Oct 2020 19:37:30
User opened query 'PV Query: As the last dose of study drug was given on 22 Sep 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	15 Oct 2020 15:44:24
User entered 'None (NONE)'	Kristy Trevino (b) (4)	07 Oct 2020 17:14:16



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:46:01
User entered '0'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:46:03
User entered '0'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:46:05
User entered 'I'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:46:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:20:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:46:19
User entered empty.	Kristy Trevino (b) (4) (b) (4)	07 Oct 2020 17:14:16

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = HE WAS ADMITTED TO THE HOSPITAL ON 10/6/20 AND WENT IN FOR SURGERY AT 19:00. However, ConProc date is 04OCT2020. Please review and reconcile data as appropriate. '(Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Dec 2020 12:50:54
Query 'Per DM CLR: SAE Narrative = HE WAS ADMITTED TO THE HOSPITAL ON 10/6/20 AND WENT IN FOR SURGERY AT 19:00. However, ConProc date is 04OCT2020. Please review and reconcile data as appropriate. ' answered with 'UPDATED NARRATIVE AND CONPROC' (Site from DM).		30 Nov 2020 16:54:02
User entered 'SUBJECT WAS CALLED FOR DAY 43 SAFETY CALL, HE THEN STATED HE WAS IN THE HOSPITAL DUE TO HAVING EMERGENCY SURGERY FOR A PERFORATED COLON , HE STATED SYMPTOMS STARTED WHEN HE WOKE UP ON SUNDAY (10/4/20) ABOUT 9:00 AM , HE WAS ADMITTED TO THE HOSPITAL ON 10/4/20 AND WENT IN FOR SURGERY ON 10/6/20 AT 19:00 . HOSPITAL RECORDS WILL BE REQUESTED AND MEDICATIONS AND ALL OTHER INFORMATION WILL BE UPDATED AS SOON AS RECORDS ARE RECEIVED.UPDATED NARRATIVE AND CONPROC' reason for change: Data Entry Error DataPoint Un-verified.		24 Nov 2020 23:35:46
		24 Nov 2020 23:34:44
		24 Nov 2020 23:34:23

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT WAS CALLED FOR DAY 43 SAFETY CALL, HE THEN STATED HE WAS IN THE HOSPITAL DUE TO HAVING EMERGENCY SURGERY FOR A PERFORATED COLON , HE STATED SYMPTOMS STARTED WHEN HE WOKE UP ON SUNDAY (10/4/20) ABOUT 9:00 AM , HE WAS ADMITTED TO THE HOSPITAL ON 10/4/20 AND WENT IN FOR SURGERY ON 10/6/20 AT 19:00 . HOSPITAL RECORDS WILL BE REQUESTED AND MEDICATIONS AND ALL OTHER INFORMATION WILL BE UPDATED AS SOON AS RECORDS ARE RECEIVED.' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 23:34:23
User opened query 'Per DM CLR: SAE Narrative = HE WAS ADMITTED TO THE HOSPITAL ON 10/6/20 AND WENT IN FOR SURGERY AT 19:00. However, ConProc date is 04OCT2020. Please review and reconcile data as appropriate. ' (Site from DM).		23 Nov 2020 23:36:29
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).		10 Nov 2020 14:01:49
User closed query 'PV Query: The discharge date was reported as 06 Oct 2020. However, it was also reported that hospitalization was prolonged due to the event of pulmonary embolism with a start date of 07 Oct 2020. Please clarify on the hospital discharge date. ' (Site from Safety).		10 Nov 2020 14:01:46
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		10 Nov 2020 14:01:43
User closed query 'PV Query: What was the anatomical location of perforation (i.e. ascending, descending, transverse colon, etc)' (Site from Safety).		10 Nov 2020 14:01:42

PRODUCTION RELEASE (v12.003  
EAB) (1725)

1794 of 2331

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. CT, xray, CBC, lactate, operative findings, histopathology, etc ). Please include units and reference ranges if applicable.' (Site from Safety).	(b) (4), (b) (6)	10 Nov 2020 14:01:38
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).		10 Nov 2020 14:01:37
Query 'PV Query: The discharge date was reported as 06 Oct 2020. However, it was also reported that hospitalization was prolonged due to the event of pulmonary embolism with a start date of 07 Oct 2020. Please clarify on the hospital discharge date. '	Darlington Akahara (b) (4)	09 Nov 2020 00:36:28
answered with 'Details will be updated once medical records become available' (Site from Safety).		
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.'	Darlington Akahara (b) (4)	09 Nov 2020 00:36:18
answered with 'Details will be updated once medical records become available' (Site from Safety).		
Query 'PV Query: What was the anatomical location of perforation (i.e. ascending, descending, transverse colon, etc)' answered with 'Details will be updated once medical records become available' (Site from Safety).	Darlington Akahara (b) (4)	09 Nov 2020 00:36:09
Query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. CT, xray, CBC, lactate, operative findings, histopathology, etc ). Please include units and reference ranges if applicable.'	Darlington Akahara (b) (4)	09 Nov 2020 00:36:02
answered with 'Details will be updated once medical records become available' (Site from Safety).		



US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
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 'Details will be updated once medical records become available' (Site from Safety).	Darlington Akahara (b) (4)	09 Nov 2020 00:35:56
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 'this is a repeat query' (Site from Safety).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:49:02
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)	06 Nov 2020 17:11:15
User opened query 'PV Query: The discharge date was reported as 06 Oct 2020. However, it was also reported that hospitalization was prolonged due to the event of pulmonary embolism with a start date of 07 Oct 2020. Please clarify on the hospital discharge date. ' (Site from Safety).		06 Nov 2020 17:10:54
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		05 Nov 2020 23:35:34
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:46:23
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'COVID-19 testing not performed, as per patient' (Site from Safety).	Antonio Gutierrez (b) (4)	04 Nov 2020 20:26:03

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: What was the underlying cause of colon perforation (i.e. tumor, diverticulitis, colitiis, foreign body, obstruction, etc)' (Site from Safety).	(b) (4), (b) (6)	29 Oct 2020 16:30:22
Query 'PV Query: What was the underlying cause of colon perforation (i.e. tumor, diverticulitis, colitiis, foreign body, obstruction, etc)' answered with 'diverticulitis' (Site from Safety).	Victoria Hernandez (b) (4)	28 Oct 2020 19:37:55
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)	15 Oct 2020 15:45:17
User opened query 'PV Query: What was the anatomical location of perforation (i.e. ascending, descending, transverse colon, etc)' (Site from Safety).		15 Oct 2020 15:44:59
User opened query 'PV Query: What was the underlying cause of colon perforation (i.e. tumor, diverticulitis, colitiis, foreign body, obstruction, etc)' (Site from Safety).		15 Oct 2020 15:44:47
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		15 Oct 2020 15:44:17
User opened query 'PV Query: Please provide any relevant laboratory/diagnostic test results (i.e. CT, xray, CBC, lactate, operative findings, histopathology, etc ). Please include units and reference ranges if applicable.' (Site from Safety).		15 Oct 2020 15:44:09
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).		15 Oct 2020 15:42:49

US3292304

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject was called for day 43 safety call, he then stated he was in the hospital due to having emergency surgery for a perforated colon , he stated symptoms started when he woke up on Sunday (10/4/20) about 9:00 am , he was admitted to the hospital on 10/6/20 and went in for surgery at 19:00 . Hospital records will be requested and medications and all other information will be updated as soon as records are received.'	Kristy Trevino (b) (4)	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Oct 2020 17:14:16

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:33:41
DataPoint Verified.		04 Nov 2020 22:51:03
User entered 'USA-US072-2020-mRNA-1273-P301000005'		02 Nov 2020 15:56:42

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:54
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 21:19:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	30 Oct 2020 21:19:02
Data point term sent to Coder	System	30 Oct 2020 21:18:38
User entered 'Pulmonary Embolism'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:52
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:51
User entered 'No (N)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:40
User entered 'No (N)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:38
User entered '7 Oct 2020'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:47
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 21:05:25
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Apr 2021 18:43:24
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	16 Apr 2021 18:43:24
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	16 Apr 2021 18:43:24
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	16 Apr 2021 18:43:02
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:36
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:36:28
DataPoint Verified.		16 Apr 2021 21:05:26
Query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	16 Apr 2021 18:43:59
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	16 Apr 2021 18:43:02
User entered '1 Apr 2021' reason for change: New Information	Antonio Gutierrez (b) (4)	16 Apr 2021 18:43:02
User opened query 'PV Query: Please provide the event end date, when available. If a new baseline has been established (diagnosis of stabilized, chronic or recurrent condition) for the subject, then the SAE is considered resolved with sequelae and an end date should be associated at that time. Please leave query open until information is available.' (Site from Safety).	(b) (4), (b) (6)	16 Feb 2021 21:14:28
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:31:25
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:31:28
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:32
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:31
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:29
User entered '0'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:27
User entered '0'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User closed query 'Per CDM Re-Query: previous response is noted; however, ICU is recorded as NO yet admission and discharge dates are not provided. Please reconcile.' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 12:54:18
Query 'Per CDM Re-Query: previous response is noted; however, ICU is recorded as NO yet admission and discharge dates are not provided. Please reconcile.' answered with 'UPDATED' (Site from DM).		24 Nov 2020 23:38:10
User opened query 'Per CDM Re-Query: previous response is noted; however, ICU is recorded as NO yet admission and discharge dates are not provided. Please reconcile.' (Site from DM).		21 Nov 2020 10:05:29
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		21 Nov 2020 10:03:48
DataPoint Verified.		04 Nov 2020 22:50:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Information is pending medical records.' (Site from System).	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:37
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	30 Oct 2020 21:18:19
User entered 'I'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 16:58:23
User entered '4 Oct 2020' reason for change: Per Query Resolution		24 Nov 2020 23:37:54
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

**Hospital Discharge Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 16:58:24
User entered '16 Oct 2020' reason for change: Per Query Resolution		24 Nov 2020 23:37:54
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 16:58:26
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	17 Nov 2020 22:29:10
Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).		17 Nov 2020 22:29:10
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	17 Nov 2020 22:29:10
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	30 Oct 2020 21:18:19
User entered 'Unknown (UNK)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Nov 2020 16:58:27
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:12
User entered '0'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:11
User entered '0'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:09
User entered '0'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:06
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:04
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:50:03
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:49:55
User entered '0'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:45:02
User entered 'l'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:49:58
User entered '0'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: If the event, pulmonary embolism, has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 19:01:16
		30 Apr 2021 17:16:59
Query 'PV Query: If the event, pulmonary embolism, has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'Patient has no sequale to this event. Patient was rx blood thinners to prevent further occurrences, therefore Indication of cmeds will be changed to Prophylaxis. Agreed by PI. ' (Site from Safety).	Nathan Cortez (b) (4)	30 Apr 2021 16:57:19
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information DataPoint Un-verified.	Nathan Cortez (b) (4)	30 Apr 2021 16:56:30
	Nathan Cortez (b) (4)	30 Apr 2021 16:40:03
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: New Information	Nathan Cortez (b) (4)	30 Apr 2021 16:40:03
User opened query 'PV Query: If the event, pulmonary embolism, has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety).	(b) (4), (b) (6)	26 Apr 2021 18:28:11
User closed query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). DataPoint Verified.		19 Apr 2021 18:36:33
		16 Apr 2021 21:05:42

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Outcome](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	Antonio Gutierrez (b) (4)	16 Apr 2021 18:44:04
	Antonio Gutierrez (b) (4)	16 Apr 2021 18:43:02
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Antonio Gutierrez (b) (4)	16 Apr 2021 18:43:02
User opened query 'PV Query: Please provide the final event outcome, when available. If the event has reached a new baseline where the subject has stabilized with ongoing symptoms/medications; then outcome would be Recovered/Resolved with sequelae with sequelae being the ongoing conditions.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	16 Feb 2021 21:14:12
		04 Nov 2020 22:48:56
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	30 Apr 2021 16:56:30
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	30 Apr 2021 16:40:03
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:48:54
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:48:45
User entered 'A perforated colon was a previously documented for this patient. This patient came in to clinic for his Visit 3 on 30OCT2020. While in clinic, the patient informed staff that he was diagnosed with a pulmonary embolism after his surgery. Patient states that he was started on blood thinners (Xarelto). Patient states that this PE prolonged his hospitalization, therefore this SAE is being submitted. Medical records for both the perforated colon and the pulmonary embolism have been requested as of 30OCT2020.'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:18:19



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	30 Oct 2020 21:18:19

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Oct 2020 21:18:19

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:33:41
DataPoint Verified.		09 Mar 2021 17:10:44
DataPoint Un-verified.		09 Mar 2021 17:08:01
DataPoint Verified.		09 Mar 2021 17:07:44
User entered 'USA-US072-2021-mRNA-1273-P301000010'	System	21 Jan 2021 17:40:38
User entered 'New'	(b) (4), (b) (6)	21 Jan 2021 17:40:38

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please review AE #s 2 and 3, as both events were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	19 Apr 2021 15:20:34
Query 'Per DM CLR: Please review AE #s 2 and 3, as both events were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' answered with 'Dates are overlapping because the second event was discovered while first event was still ongoing.' (Site from DM).	Antonio Gutierrez (b) (4)	16 Apr 2021 18:45:47
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:08
User opened query 'Per DM CLR: Please review AE #s 2 and 3, as both events were noted as ongoing and have overlapping dates. Please reconcile and update so there is no overlap. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 11:28:48
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Pulmonary vascular disorders, HLT: Pulmonary thrombotic and embolic conditions, PT: Pulmonary embolism, LLT: Pulmonary embolism - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 19:16:03
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	22 Jan 2021 19:16:03
Data point term sent to Coder	System	20 Jan 2021 18:27:15
User entered 'RIGHT LUNG PULMONARY EMBOLI' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	20 Jan 2021 18:27:13
Data point term sent to Coder	System	20 Jan 2021 18:08:00
User entered 'Left Lung Pulmonary Emboli'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:10
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:11
User entered 'No (N)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:13
User entered 'No (N)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:15
User entered '15 Jan 2021'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

**Start time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:17
User entered empty.	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:04:43
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	16 Apr 2021 18:45:12
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	16 Apr 2021 18:45:12
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:18
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:33:23
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6)	19 Apr 2021 18:04:44
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' answered with 'updated' (Site from Safety). DataPoint Un-verified.	Antonio Gutierrez (b) (4) (b) (4)	16 Apr 2021 18:45:54
User entered '1 Apr 2021' reason for change: New Information DataPoint Verified.	Antonio Gutierrez (b) (4) (b) (4), (b) (6)	16 Apr 2021 18:45:12 01 Mar 2021 21:51:21
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4), (b) (6) Antonio Gutierrez (b) (4)	28 Jan 2021 20:55:16 20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

**End time (00:00-23:59)**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:22
User entered empty.	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:24
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:27
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:30
User entered '0'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:51:32
User entered '0'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:52:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).		26 Jan 2021 13:53:25
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Patient not yet d/c'ed and not in ICU' (Site from System).	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:58
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	20 Jan 2021 18:07:37
User entered 'I'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

**Hospital Admission Date** (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:52:38
User entered '15 Jan 2021'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per CDM: Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	26 Apr 2021 09:17:46
		22 Apr 2021 21:44:12
Query 'Per CDM: Please update 'Hospital Discharge Date' once data becomes known. Thanks' answered by data change (Site from DM). DataPoint Un-verified.	System	21 Apr 2021 19:35:13
	Kristy Trevino (b) (4)	21 Apr 2021 19:35:13
	(b) (4)	
User entered '23 Jan 2021' reason for change: New Information DataPoint Verified.	Kristy Trevino (b) (4)	21 Apr 2021 19:35:13
	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:52:41
Query '(Pending MR) 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.' canceled (Site from Safety).		16 Feb 2021 21:19:48
User opened query '(Pending MR) 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).		28 Jan 2021 20:54:56
User opened query 'Per CDM: Please update 'Hospital Discharge Date' once data becomes known. Thanks' (Site from DM). User entered empty.		26 Jan 2021 13:53:48
	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:52:43
User entered 'No (N)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:52:44
User entered empty.	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:52:47
User entered '0'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:52:48
User entered '0'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:52:52
User entered '0'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:52:59
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:53:01
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:53:13
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:53:15
User entered '0'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:53:18
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE within this time frame. Please update to record the ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM). User entered 'I'	(b) (4)	16 Feb 2021 11:29:01
	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37



**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:53:21
User entered '0'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

[Outcome](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 18:33:30
DataPoint Verified.		16 Apr 2021 21:06:07
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	16 Apr 2021 18:46:10
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	16 Apr 2021 18:45:12
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: New Information	Antonio Gutierrez (b) (4)	16 Apr 2021 18:45:12
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:53:22
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		28 Jan 2021 20:55:30
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 21:53:24
User entered empty.	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'IQVIA Medical query: Please confirm whether the subject has any risk factors for development of right lung pulmonary emboli considering that anticoagulation was ongoing at the time of the event (i.e. subtherapeutic anticoagulation, blood clotting disorders, immobilization, trauma).' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 20:37:19
User opened query 'PV Query: Please send a hospital discharge summary and any relevant laboratory and diagnostic test results with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		01 Mar 2021 21:55:29
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' canceled (Site from Safety).		16 Feb 2021 21:26:24
User opened query 'Per DM CLR: Narrative indicates that the subject had CT Scan. however, there is no recorded Concomitant Procedure that match the information. Please update to record the corresponding procedure as appropriate. Otherwise, clarify.' (Site from DM).		16 Feb 2021 21:20:29
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).		16 Feb 2021 11:29:26
		28 Jan 2021 20:55:46

US3292304

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:30:09

[Narrative](#)

Audit	User	Time (GMT)
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)	28 Jan 2021 20:55:39
User entered 'PATIENT HAS BEEN FOLLOWED REGULARLY BY HIS PULMONOLOGIST DUE TO PULMONARY EMBOLISM REPORTED EARLIER IN L LUNG. FOLLOWING VISIT ON 15JAN2021, DOCTOR ORDERED A STAT CT SCAN FOLLOWING PT REPORT OF SMALL AMOUNTS OF BLOOD IN HIS SPIT IN THE MORNINGS. SCAN SHOWED ORIGINAL EMBOLISM IN L LUNG STILL PRESENT ALONG WITH TWO NEW EMBOLI IN R LUNG. PATIENT WAS ADMITTED AND HAS BEEN HOSPITALIZED SINCE WITH ESTIMATED DISCHARGE DATE OF 21JAN2021. MEDICAL RECORDS WILL BE REQUESTED.' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	20 Jan 2021 18:27:13
User entered 'Patient has been followed regularly by his pulmonologist due to pulmonary embolism reported earlier in R lung. Following visit on 15JAN2021, doctor ordered a STAT CT scan following pt report of small amounts of blood in his spit in the mornings. Scan showed original embolism in R lung still present along with two new emboli in L lung. Patient was admitted and has been hospitalized since with estimated discharge date of 21JAN2021. Medical records will be requested.'	Antonio Gutierrez (b) (4)	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Jan 2021 18:07:37

**US3292304**

**Folder: Adverse Events**

**Form: Adverse Events (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	20 Jan 2021 18:07:37



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:30:09

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:31
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User closed query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 14:22:48
Query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'Medication added to conmed log. ' (Site from DM).		14 Apr 2021 21:28:58
User opened query 'Per DM CLR: Per Diary Dose 2 Day 2, Headache (General) = Repeated use of over-the-counter pain reliever > 24 hours or some interference with activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).		03 Feb 2021 11:40:18
User closed query 'Per ETRTR: SAE "Perforated colon" indicates Concomitant procedures were performed. Please update Concomitant Procedures as applicable, thanks.' (Site from CRA).		15 Nov 2020 20:59:03
Query 'Per ETRTR: SAE "Perforated colon" indicates Concomitant procedures were performed. Please update Concomitant Procedures as applicable, thanks.' answered with 'updated procedures' (Site from CRA).	Victoria Hernandez (b) (4)	28 Oct 2020 19:32:48

US3292304

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination Summary**

**Generated On: 09 Jun 2021 16:30:09**

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
User opened query 'Per ETRTR: SAE "Perforated colon" indicates Concomitant procedures were performed. Please update Concomitant Procedures as applicable, thanks.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	09 Oct 2020 22:51:32
		01 Oct 2020 19:32:12
User entered 'Yes (Y)'		27 Aug 2020 15:25:29

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:34:12
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: PIPERAZINE DERIVATIVES, PRODUCT: CETIRIZINE HYDROCHLORIDE, PRODUCTSYNONYM: ZYRTEC [CETIRIZINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:27:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:27:26
Data point term sent to Coder User entered 'zyrtec'	System (b) (4), (b) (6)	27 Aug 2020 15:26:29 27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:13
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:26:10

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:34:15
User entered 'seasonal allergies'		27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:34:19
User entered '10'		27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:21
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:26:10

US3292304

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:26
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:26:10



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:24
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Aug 2020 15:26:10

US3292304

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:28
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:30
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:33
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:26:10

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:30:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:35
User entered 'un UNK 2000'	(b) (4), (b) (6)	27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:39
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:44
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:26:10



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:34:46
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:26:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:26:10

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:35:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: METHYLCELLULOSE, PRODUCTSYNONYM: CITRUCEL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 16:38:35
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Aug 2020 16:38:35
Data point term sent to Coder	System	27 Aug 2020 15:27:30
User entered 'citrucel'	(b) (4), (b) (6)	27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:55:52
User closed query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		07 Dec 2020 11:48:49
Query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	03 Dec 2020 19:47:37
DataPoint Un-verified.	Victoria Hernandez (b) (4)	03 Dec 2020 19:47:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	03 Dec 2020 19:47:30
User opened query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:52:37
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' (Site from DM).		27 Nov 2020 08:52:37
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' answered with 'As per patient on 06NOV2020, not given as prophylactic or preventative measure. ' (Site from DM).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:40:31

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
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' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 14:36:28
		01 Oct 2020 19:35:19
User entered 'No (N)'		27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:35:21
User entered 'supplement'		27 Aug 2020 15:26:52



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:35:22
User entered '500'	(b) (4), (b) (6)	27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:35:24
User entered 'mg (mg)'		27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:35:27
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:35:54
User entered 'once daily (QD)'		27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:35:56
User entered empty.		27 Aug 2020 15:26:52

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:35:58
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:26:52

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 01 Oct 2020 19:36:08
User entered empty.		27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:10
User entered 'un Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 15:26:52



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:36:12
User entered '0'		27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:14:17
DataPoint Un-verified.	Gerardo Pena (b) (4)	20 Nov 2020 15:29:24
User entered 'No (N)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 15:29:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:36:14
User entered 'Yes (Y)'		27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:14:24
DataPoint Un-verified.	Gerardo Pena (b) (4)	20 Nov 2020 15:29:24
User entered '4 Oct 2020' reason for change: Data Entry Error	Gerardo Pena (b) (4)	20 Nov 2020 15:29:24
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:36:15
User entered empty.		27 Aug 2020 15:26:52

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:36:17
User entered 'No (N)'		27 Aug 2020 15:26:52

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User entered 'I'	System	27 Aug 2020 15:26:52

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User entered 'I'	System	27 Aug 2020 15:26:52

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:02
User entered '804 (804)'	System	27 Aug 2020 15:26:52

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:36:41
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: PROBIOTICS NOS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 11:59:40
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 11:59:40
Data point term sent to Coder	System	27 Aug 2020 15:27:33
User entered 'probiotic'	(b) (4), (b) (6)	27 Aug 2020 15:27:25



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:55:56
User closed query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		07 Dec 2020 11:48:56
Query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	03 Dec 2020 19:48:56
DataPoint Un-verified.	Victoria Hernandez (b) (4)	03 Dec 2020 19:48:32
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Victoria Hernandez (b) (4)	03 Dec 2020 19:48:32
User opened query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:52:04
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).		27 Nov 2020 08:52:04
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 'As per patient on 06NOV2020, not given as prophylactic or preventative measure.' (Site from DM).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:40:16

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 10:23:42
		01 Oct 2020 19:36:42
User entered 'No (N)'		27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:43
User entered 'digestion supplement'	(b) (4), (b) (6)	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:45
User entered 'I'	(b) (4), (b) (6)	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:48
User entered 'tablet (TABLET)'	(b) (4), (b) (6)	27 Aug 2020 15:27:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:51
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:52
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 15:27:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:53
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:27:25



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:54
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:56
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:27:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:30:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:36:57
User entered 'un Feb 2020'	(b) (4), (b) (6)	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:37:01
User entered '0'	(b) (4), (b) (6)	7 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:37:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:37:04
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:37:05
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 15:27:25



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 15:27:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:27:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:37:25
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:36:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:36:56
Data point term sent to Coder	System	27 Aug 2020 15:28:37
User entered 'Mega Man Sport Multivitamin'	(b) (4), (b) (6)	27 Aug 2020 15:28:30

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:56:02
User closed query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		07 Dec 2020 11:49:07
Query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	03 Dec 2020 19:49:31
DataPoint Un-verified.		
	Victoria Hernandez (b) (4)	03 Dec 2020 19:49:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Victoria Hernandez (b) (4)	03 Dec 2020 19:49:24
User opened query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:47:49
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).		27 Nov 2020 08:47:49
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 'As per patient on 06NOV2020, not given as prophylactic or preventative measure.' (Site from DM).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:45:44

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 10:21:28
		01 Oct 2020 19:37:26
User entered 'No (N)'		27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:37:28
User entered 'health supplement'		27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:37:31
User entered 'I'	(b) (4), (b) (6)	27 Aug 2020 15:28:30

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:37:34
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Aug 2020 15:28:30



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:09
User entered 'pk'	(b) (4), (b) (6)	27 Aug 2020 15:28:30

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:09

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:11
User entered 'every other day (QOD)'	(b) (4), (b) (6)	27 Aug 2020 15:28:30

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:16
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:19
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:21
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:22
User entered 'un May 2020'	(b) (4), (b) (6)	27 Aug 2020 15:28:30

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:37
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:42
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:28:30



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:44
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Aug 2020 15:28:30

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:28:30

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:38:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:33:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Sep 2020 22:33:54
Data point term sent to Coder	System	27 Aug 2020 15:29:40
User entered 'Mega Man Perf Multivitamin'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:56:05
User closed query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' (Site from DM).		07 Dec 2020 11:49:14
Query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	03 Dec 2020 19:49:49
DataPoint Un-verified.	Victoria Hernandez (b) (4)	03 Dec 2020 19:49:42
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	
	Victoria Hernandez (b) (4)	03 Dec 2020 19:49:42
User opened query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:49:22
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).		27 Nov 2020 08:49:22
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 'As per patient on 06NOV2020, not given as prophylactic or preventative measure. ' (Site from DM).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:45:58

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
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). DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 10:21:44
		01 Oct 2020 19:38:52
User entered 'No (N)'		27 Aug 2020 15:29:10



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:54
User entered 'health supplement'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:38:55
User entered 'I'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:02
User entered 'Other (OTHER)'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:03
User entered 'pk'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:05
User entered 'every other day (QOD)'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:06
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:08
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:09
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:29:10



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:11
User entered 'un May 2020'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:12
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:14
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:15
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:39:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	27 Aug 2020 15:29:10

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 15:29:10



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:41:43
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:28:10
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:28:10
Data point term sent to Coder	System	27 Aug 2020 15:30:41
User entered 'Tylenol'	(b) (4), (b) (6)	27 Aug 2020 15:29:44

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:56:11
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).		07 Dec 2020 11:46:30
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)	03 Dec 2020 19:50:43
DataPoint Un-verified.	(b) (4)	
	Victoria Hernandez (b) (4)	03 Dec 2020 19:50:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	03 Dec 2020 19:50:31
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)	11 Nov 2020 11:06:46
DataPoint Verified.		01 Oct 2020 19:41:44
User entered 'No (N)'		27 Aug 2020 15:29:44

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User closed query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update the indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 09:33:57
Query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update the indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' answered with 'per subject; used for pain prevention' (Site from DM).	Dawn Killian (b) (4) (b) (4)	13 Apr 2021 19:18:16
User opened query 'Per DM CLR: Please note this medication is not expected to be given as a prophylaxis. It is typically used to treat a medical diagnosis. Please review and update the indication if applicable or please clarify. If a condition is added to the indication please ensure MH/ AE eCRF is updated to reflect this update.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:29:46
DataPoint Verified.		01 Oct 2020 19:41:46
User entered 'pain preventative'		27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:41:49
User entered '500'		27 Aug 2020 15:29:44

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:41:50
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:41:51
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:41:53
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Aug 2020 15:29:44

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:41:54
User entered empty.		27 Aug 2020 15:29:44



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:41:55
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:41:57
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:29:44

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:09

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:41:58
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:41:59
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:42:01
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:42:02
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:29:44

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:30:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:42:04
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:29:44



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:29:44

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:29:44

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:21
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)	15 Sep 2020 19:59:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	15 Sep 2020 19:59:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: HERBAL CARMINATIVES, PRODUCT: CURCUMA LONGA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:28:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:28:06
Data point term sent to Coder	System	27 Aug 2020 15:30:44
User entered 'tumeric'	(b) (4), (b) (6)	27 Aug 2020 15:30:16

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:56:16
User closed query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		07 Dec 2020 11:49:32
Query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	03 Dec 2020 19:51:04
DataPoint Un-verified.	Victoria Hernandez (b) (4)	03 Dec 2020 19:50:55
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	03 Dec 2020 19:50:55
User opened query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:50:32
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).		27 Nov 2020 08:50:32

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
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 'As per patient on 06NOV2020, not given as prophylactic or preventative measure. ' (Site from DM).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:46:11
User opened query 'Per CDM: Response is recorded as No; however, indication is recorded as health promotion measure. Please clarify if this was given a a prophylactic or preventative measure. If yes, please update accordingly' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 10:22:22
DataPoint Verified.		01 Oct 2020 19:42:22
User entered 'No (N)'		27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:42:24
User entered 'health supplement'		27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:42:25
User entered '500'		27 Aug 2020 15:30:16

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:42:27
User entered 'mg (mg)'		27 Aug 2020 15:30:16



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:42:29
User entered empty.		27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:42:30
User entered 'as needed (PRN)'		27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:42:32
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:42:33
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:42:34
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:42:36
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:42:37
User entered '0'		27 Aug 2020 15:30:16

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:30:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:48
DataPoint Un-verified.	Gerardo Pena (b) (4)	20 Nov 2020 15:30:15
User entered 'No (N)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 15:30:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:42:38
User entered 'Yes (Y)'		27 Aug 2020 15:30:16



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

**If not Ongoing, End date (dd MMM yyyy)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:50
DataPoint Un-verified.	Gerardo Pena (b) (4)	20 Nov 2020 15:30:15
User entered '4 Oct 2020' reason for change: Data Entry Error	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 15:30:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:42:40
User entered empty.		27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:42:41
User entered 'No (N)'		27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User entered empty.	System	27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User entered empty.	System	27 Aug 2020 15:30:16

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (7)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:09
User entered empty.	System	27 Aug 2020 15:30:16

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:43:10
User coded data point as ATC: VARIOUS, ATC: UNSPECIFIED HERBAL AND TRADITIONAL MEDICINE, PRODUCT: ZINGIBER OFFICINALE, PRODUCTSYNONYM: GINGER [ZINGIBER OFFICINALE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 00:54:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Sep 2020 00:54:02
Data point term sent to Coder	System	27 Aug 2020 15:31:44
User entered 'ginger'	(b) (4), (b) (6)	27 Aug 2020 15:30:46

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Mar 2021 21:56:55
User closed query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).		07 Dec 2020 11:49:41
Query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	03 Dec 2020 19:51:21
DataPoint Un-verified.	Victoria Hernandez (b) (4)	03 Dec 2020 19:51:14
User entered 'Yes (Y)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	03 Dec 2020 19:51:14
User opened query 'Per CDM: Response noted; however, this medication appears to be given as prophylaxis. Note that supplements, vitamins, contraceptives/birth control, prophylactically indicated drugs, & heart health medications are examples of it. Update response as appropriate. Otherwise, clarify' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 08:51:37
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).		27 Nov 2020 08:51:37

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
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 'As per patient on 06NOV2020, not given as prophylactic or preventative measure. ' (Site from DM).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:46:22
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)	05 Nov 2020 10:22:44
DataPoint Verified.		01 Oct 2020 19:43:11
User entered 'No (N)'		27 Aug 2020 15:30:46



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:43:13
User entered 'health supplement'	(b) (4), (b) (6)	27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:43:14
User entered '1000'	(b) (4), (b) (6)	27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:43:16
User entered 'mg (mg)'		27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:43:19
User entered empty.		27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:43:21
User entered 'as needed (PRN)'		27 Aug 2020 15:30:46

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:43:22
User entered empty.		27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:43:24
User entered 'Oral (ORAL)'		27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:43:25
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:30:46



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:43:27
User entered 'un May 2020'		27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:43:28
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:30:46

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:56:58
DataPoint Un-verified.	Gerardo Pena (b) (4)	20 Nov 2020 15:30:33
User entered 'No (N)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:30
User entered 'Yes (Y)'		27 Aug 2020 15:30:46

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:57:00
DataPoint Un-verified.	Gerardo Pena (b) (4)	20 Nov 2020 15:30:33
User entered '4 Oct 2020' reason for change: Data Entry Error	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 15:30:33
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:43:32
User entered empty.		27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:43:33
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User entered empty.	System	27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User entered empty.	System	27 Aug 2020 15:30:46

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (8)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:12
User entered empty.	System	27 Aug 2020 15:30:46



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:44:28
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: OTHER SYSTEMIC DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: LEUKOTRIENE RECEPTOR ANTAGONISTS, PRODUCT: MONTELUKAST SODIUM, PRODUCTSYNONYM: SINGULAIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:28:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	27 Aug 2020 19:28:23
Data point term sent to Coder	System	27 Aug 2020 15:31:45
User entered 'singulair'	(b) (4), (b) (6)	27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:44:29
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:31:24

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:10:41
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 'mountain cedar allergy is seasonal.' (Site from DM).	Gerardo Pena (b) (4)	09 Nov 2020 19:38:55
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:15:27
DataPoint Verified.		01 Oct 2020 19:44:30
User entered 'seasonal allergies'		27 Aug 2020 15:31:24

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:09

[Dose per administration](#)

Audit	User	Time (GMT)
User closed query 'Please update Con med source.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:54:25
		16 Apr 2021 17:54:23
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
	(b) (4)	
Query 'Please update Con med source.' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	13 Apr 2021 19:20:01
	(b) (4)	
User opened query 'Please update Con med source.' (Site from CRA).	(b) (4), (b) (6)	01 Mar 2021 21:57:49
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).		07 Dec 2020 11:27:02
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'updated' (Site from DM).	Victoria Hernandez (b) (4)	03 Dec 2020 19:53:43
	(b) (4)	
DataPoint Un-verified.	Victoria Hernandez (b) (4)	03 Dec 2020 19:52:15
	(b) (4)	
User entered '10' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	03 Dec 2020 19:52:15
	(b) (4)	
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Oct 2020 14:15:39
DataPoint Verified.		01 Oct 2020 19:44:32
User entered '1'		27 Aug 2020 15:31:24

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:09

[Dose unit](#)

Audit	User	Time (GMT)
User closed query 'Please update Con med source.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:54:28
DataPoint Verified.		16 Apr 2021 17:54:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
Query 'Please update Con med source.' answered with 'updated' (Site from CRA).	(b) (4)	
	Dawn Killian (b) (4)	13 Apr 2021 19:20:04
User opened query 'Please update Con med source.' (Site from CRA).	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	01 Mar 2021 21:57:57
	Victoria Hernandez (b) (4)	03 Dec 2020 19:52:15
	(b) (4)	
User entered 'mg (mg)' reason for change: Data Entry Error	Victoria Hernandez (b) (4)	03 Dec 2020 19:52:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:44:33
User entered 'tablet (TABLET)' reason for change: Data Entry Error	Dawn Killian (b) (4)	24 Sep 2020 01:29:47
User entered 'Other (OTHER)'	(b) (4)	
	(b) (4), (b) (6)	27 Aug 2020 15:31:24

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:30:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User closed query 'Per DM CLR: Please review "Other Unit" as there is an available option for "tablet" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 11:07:29
DataPoint Verified.		01 Oct 2020 19:44:35
Query 'Per DM CLR: Please review "Other Unit" as there is an available option for "tablet" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	24 Sep 2020 01:30:05
User entered empty; reason for change Data Entry Error	(b) (4)	24 Sep 2020 01:29:47
User opened query 'Per DM CLR: Please review "Other Unit" as there is an available option for "tablet" in the listed choices for unit. Please review and select an appropriate option from the list provided in the CRF and amend as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Sep 2020 04:15:45
User entered 'pill'		7 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:44:37
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:44:38
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:31:24



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:44:39
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:46:38
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:46:44
User entered 'un UNK 2010'	(b) (4), (b) (6)	27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:46:43
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:46:46
User entered 'Yes (Y)'		27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

*If not Ongoing, End date (dd MMM yyyy)*

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:46:47
User entered empty.		27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:46:48
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:31:24



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:31:24

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (9)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 15:31:24

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:47:08
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE, PRODUCTSYNONYM: DICYCLOMINE [DICYCLOVERINE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:57:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	31 Aug 2020 13:57:48
Data point term sent to Coder	System	27 Aug 2020 15:32:46
User entered 'dicyclomine'	(b) (4), (b) (6)	27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:55:33
User entered 'No (N)'		27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:55:41
User entered 'diverticulosis'		27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:55:42
User entered '10'		27 Aug 2020 15:32:07

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:55:45
User entered 'mg (mg)'		27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:55:50
User entered empty.		27 Aug 2020 15:32:07



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:55:51
User entered 'once daily (QD)'		27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:55:53
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:32:07

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:56:02
User entered 'Oral (ORAL)'		27 Aug 2020 15:32:07

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	01 Oct 2020 19:56:05
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	01 Oct 2020 19:56:07
User entered 'un Jul 2020'		27 Aug 2020 15:32:07

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:56:08
User entered '0'		27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:58:06
DataPoint Un-verified.	Gerardo Pena (b) (4)	20 Nov 2020 15:30:51
User entered 'No (N)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 15:30:51
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Oct 2020 19:56:09
User entered 'Yes (Y)'		27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	01 Mar 2021 21:58:08
DataPoint Un-verified.	Gerardo Pena (b) (4)	20 Nov 2020 15:30:51
User entered '4 Oct 2020' reason for change: Data Entry Error	(b) (4) Gerardo Pena (b) (4)	20 Nov 2020 15:30:51
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:56:11
User entered empty.		27 Aug 2020 15:32:07



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:30:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	01 Oct 2020 19:56:13
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 15:32:07

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User entered 'I'	System	27 Aug 2020 15:32:07

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User entered 'I'	System	27 Aug 2020 15:32:07

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (10)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:16
User entered '804 (804)'	System	27 Aug 2020 15:32:07

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 17:00:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Apr 2021 17:00:24
Data point term sent to Coder	System	30 Apr 2021 16:59:18
Coding entries removed.	Nathan Cortez (b) (4)	30 Apr 2021 16:58:48
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:55:27
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: RIVAROXABAN, PRODUCTSYNONYM: XARELTO - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:22:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Oct 2020 21:22:02
Data point term sent to Coder	System	30 Oct 2020 21:20:40
User entered 'Xarelto'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered 'No (N)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:44
Data hard locked.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	02 May 2021 04:57:21
DataPoint Un-verified.		30 Apr 2021 17:18:37
Signature has been broken.	Nathan Cortez (b) (4)	30 Apr 2021 16:58:48
User entered 'Prophylaxis' reason for change: Data Entry Error	Nathan Cortez (b) (4)	30 Apr 2021 16:58:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered 'Pulmonary Embolism'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered '20'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered 'mg (mg)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered 'once daily (QD)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered 'Oral (ORAL)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered '22 Oct 2020'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered '0'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:15:13
DataPoint Un-verified.	Gerardo Pena (b) (4)	03 Mar 2021 18:05:54
User entered 'No (N)' reason for change: New Information	(b) (4) Gerardo Pena (b) (4)	03 Mar 2021 18:05:54
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:15:15
DataPoint Un-verified.	Gerardo Pena (b) (4)	03 Mar 2021 18:05:54
	(b) (4)	
User entered '15 Jan 2021' reason for change: New Information	Gerardo Pena (b) (4)	03 Mar 2021 18:05:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered empty.	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:30:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 22:55:27
User entered 'No (N)'	Antonio Gutierrez (b) (4)	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User entered 'I'	System	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User entered 'I'	System	30 Oct 2020 21:20:21

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (11)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:21
User entered '804 (804)'	System	30 Oct 2020 21:20:21

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 17:11:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	30 Apr 2021 17:11:55
Data point term sent to Coder	System	30 Apr 2021 16:59:19
Coding entries removed.	Nathan Cortez (b) (4)	30 Apr 2021 16:59:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:17:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: VITAMIN K ANTAGONISTS, PRODUCT: WARFARIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 18:04:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 18:04:57
Data point term sent to Coder	System	03 Mar 2021 18:04:26
User entered 'warfarin'	Gerardo Pena (b) (4)	03 Mar 2021 18:04:18

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:17:27
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:44
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 17:19:11
DataPoint Un-verified.	Nathan Cortez (b) (4)	30 Apr 2021 16:59:01
Signature has been broken.	Nathan Cortez (b) (4)	30 Apr 2021 16:59:01
User entered 'Prophylaxis' reason for change: Data Entry Error	Nathan Cortez (b) (4)	30 Apr 2021 16:59:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:17:30
User entered 'pulmonary embolism'	Gerardo Pena (b) (4)	03 Mar 2021 18:04:18
	(b) (4)	

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:17:31
User entered '7.5'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:17:53
User entered 'mg (mg)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:10
User entered empty.	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:13
User entered 'other (OTHER)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:20
User entered 'QD (Mon to Fri)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:33
User entered 'Oral (ORAL)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:42
User entered empty.	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:40
User entered '16 Jan 2021'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:44
User entered '0'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

[Ongoing?](#)

Audit	User	Time (GMT)
User closed query 'Answer not present in source. Please provide.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:54:57
DataPoint Verified.		16 Apr 2021 17:54:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
Query 'Answer not present in source. Please provide.' answered with 'updated' (Site from CRA).	(b) (4)	
User opened query 'Answer not present in source. Please provide.' (Site from CRA).	Dawn Killian (b) (4)	13 Apr 2021 19:20:33
User entered 'Yes (Y)'	(b) (4)	
	(b) (4), (b) (6)	09 Mar 2021 17:15:49
	Gerardo Pena (b) (4)	03 Mar 2021 18:04:18
	(b) (4)	

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:46
User entered empty.	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:30:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:17:50
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:04:18

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 18:04:18

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 18:04:18

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (12)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 18:04:18



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	15 Apr 2021 13:42:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 13:42:26
Data point term sent to Coder Query 'CDM-Coding: The trade name PROTONIX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	System Coder Import (b) (4)	15 Apr 2021 12:29:00 15 Apr 2021 12:28:47
' canceled (Site from System). User opened query 'CDM-Coding: The trade name PROTONIX can be referred as multiple ingredients in the standard coding dictionary. Please enter the active ingredient(s) with drug name in drug name field and please make your changes to the reported term. Thank you.	Coder Import (b) (4) (b) (4)	15 Apr 2021 06:55:40
' (Site from System). Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	14 Apr 2021 21:07:29 14 Apr 2021 21:06:46

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: PROTON PUMP INHIBITORS, PRODUCT: PANTOPRAZOLE SODIUM SESQUIHYDRATE, PRODUCTSYNONYM: PROTONIX [PANTOPRAZOLE SODIUM SESQUIHYDRATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:37:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Mar 2021 09:37:30
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:27:27
Data point term sent to Coder	System	03 Mar 2021 18:05:26
User entered 'protonix'	Gerardo Pena (b) (4)	03 Mar 2021 18:05:25
	(b) (4)	

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:27:29
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Please provide update to Con med source.' (Site from CRA).	(b) (4), (b) (6)	29 Apr 2021 15:19:37
Query 'Please provide update to Con med source.' answered with 'Updated.' (Site from CRA).		28 Apr 2021 20:39:23
User opened query 'Please provide update to Con med source.' (Site from CRA).		16 Apr 2021 17:55:50
DataPoint Verified.		16 Apr 2021 17:55:20
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:36:15
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	16 Apr 2021 09:34:25
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'Updated' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 21:07:16
DataPoint Un-verified.	(b) (4), (b) (6)	14 Apr 2021 21:06:46
User entered 'HEALTH SUPPLEMENT' reason for change: Data Entry Error		14 Apr 2021 21:06:46
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).		24 Mar 2021 11:01:59
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:29:30
User entered 'prophylaxis'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:29:32
User entered '40'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:29:34
User entered 'mg (mg)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:29:36
User entered empty.	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:31:12
User entered 'once daily (QD)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25



US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:31:14
User entered empty.	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:31:26
User entered 'Oral (ORAL)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:31:27
User entered empty.	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:31:29
User entered '17 Jan 2021'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:31:32
User entered '0'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:34:06
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:38:01
User entered empty.	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:30:09

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 17:18:56
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	03 Mar 2021 18:05:25



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	03 Mar 2021 18:05:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 18:05:25

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (13)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	03 Mar 2021 18:05:25

US3292304

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:30:09

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.	(b) (4)	16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Apr 2021 21:30:00
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 21:30:00
Data point term sent to Coder	System	14 Apr 2021 21:29:08
User entered 'Tylenol'	(b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered 'Headache (reactogenicity)'	(b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered '500'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered 'No (N)'	(b) (4), (b) (6)	14 Apr 2021 21:28:40



**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

**If not Ongoing, End date (*dd MMM yyyy*)**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered '23 Sep 2020'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
DataPoint Verified.		16 Apr 2021 17:56:06
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:36:15
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
User entered empty.	System	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
User entered empty.	System	14 Apr 2021 21:28:40

**US3292304**

**Folder: Concomitant Medication and Vaccination (1)**

**Form: Prior/Concomitant Medication and Vaccination (14)**

**Generated On: 09 Jun 2021 16:30:09**

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 04:57:26
User entered empty.	System	14 Apr 2021 21:28:40

US3292304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:30:09

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:31
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	04 Nov 2020 22:56:02
User entered 'Yes (Y)'	Victoria Hernandez (b) (4)	28 Oct 2020 19:21:08

US3292304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:30:09

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:44:55
User closed query 'Procedure missing in Concomitant Procedure log. Please provide.' (Site from CRA).	(b) (4), (b) (6)	16 Apr 2021 17:44:53
Query 'Procedure missing in Concomitant Procedure log. Please provide.' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4) (b) (4)	13 Apr 2021 19:26:43
User opened query 'Procedure missing in Concomitant Procedure log. Please provide.' (Site from CRA).	(b) (4), (b) (6)	09 Mar 2021 17:54:20
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Feb 2021 14:08:28
User entered '6 Oct 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	24 Nov 2020 23:32:02
User entered '4 Oct 2020'	Victoria Hernandez (b) (4) (b) (4)	28 Oct 2020 19:32:29

**US3292304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:44:56
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Ileostomy'	(b) (4) Victoria Hernandez (b) (4)	28 Oct 2020 19:32:29



**US3292304**

**Folder: Concomitant Procedures (1)**

**Form: Concomitant Procedures (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:44:58
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered 'Adverse Event (AE)'	(b) (4) Victoria Hernandez (b) (4)	28 Oct 2020 19:32:29

US3292304

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:30:09

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 17:45:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered empty.	(b) (4) Victoria Hernandez (b) (4)	28 Oct 2020 19:32:29

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'USA-US072-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Douglas'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Denham'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered '7940 Floyd Curl Drive'	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:28:55
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered '5430 Fredericksburg Road, Suite 200'	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:50:36
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered '7940 Floyd Curl Drive'		08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'San Antonio'		08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered empty.	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:29:01
User closed query 'Please verify if the State should be entered and update.' (Site from CRA).		06 Nov 2020 18:28:59
Query 'Please verify if the State should be entered and update.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:18
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User opened query 'Please verify if the State should be entered and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 23:01:39
Reviewed for Safety.		02 Nov 2020 15:56:50
Un-reviewed for Safety.	System	29 Oct 2020 16:30:50
DataPoint Un-verified.	System	29 Oct 2020 16:30:50
User entered empty.	System	29 Oct 2020 16:30:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'Texas'	Victoria Hernandez (b) (4)	14 Oct 2020 15:28:18

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered '78229'	System	08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'US'	System	08 Oct 2020 12:03:10

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 19:03:53
User entered '5'	System	19 Apr 2021 18:37:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
User entered '4'	System	25 Nov 2020 20:02:58
User entered '3'	System	02 Nov 2020 15:57:06
User entered '2'	System	29 Oct 2020 16:30:50
User entered '1'	System	08 Oct 2020 12:03:10

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'USA-US072-2020-MRNA-1273-P301000005'		08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'		08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'		08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Douglas'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Denham'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered '7940 Floyd Curl Drive'	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:28:55
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered '5430 Fredericksburg Road, Suite 200'	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:50:36
DataPoint Verified.		
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered '7940 Floyd Curl Drive'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'San Antonio'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered empty.	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:29:01
User closed query 'Please verify if the State should be entered and update.' (Site from CRA).		06 Nov 2020 18:28:59
Query 'Please verify if the State should be entered and update.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:18
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User opened query 'Please verify if the State should be entered and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 23:01:39
Reviewed for Safety.		02 Nov 2020 15:56:50
Un-reviewed for Safety.	System	29 Oct 2020 16:30:50
DataPoint Un-verified.	System	29 Oct 2020 16:30:50
User entered empty.	System	29 Oct 2020 16:30:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'Texas'	Victoria Hernandez (b) (4)	14 Oct 2020 15:28:18

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered '78229'	System	08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'US'	System	08 Oct 2020 12:03:10

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 19:03:53
User entered '5'	System	19 Apr 2021 18:37:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
User entered '4'	System	25 Nov 2020 20:02:58
User entered '3'	System	02 Nov 2020 15:57:06
User entered '2'	System	29 Oct 2020 16:30:50
User entered '1'	System	08 Oct 2020 12:03:10

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Oct 2020 19:50:36
User entered '08/Oct/2020 08:03'	System	08 Oct 2020 12:03:10

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:30:09

**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)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4)	29 Oct 2020 16:30:40
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:50:36
User entered 'l'		08 Oct 2020 12:03:10

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'USA-US072-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'		08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Douglas'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Denham'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered '7940 Floyd Curl Drive'	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:28:55
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered '5430 Fredericksburg Road, Suite 200'	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:50:36
DataPoint Verified.		
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered '7940 Floyd Curl Drive'		08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'San Antonio'	System	08 Oct 2020 12:02:45



US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered empty.	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:29:01
User closed query 'Please verify if the State should be entered and update.' (Site from CRA).		06 Nov 2020 18:28:59
Query 'Please verify if the State should be entered and update.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:18
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User opened query 'Please verify if the State should be entered and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 23:01:39
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:56:50
Un-reviewed for Safety.	System	29 Oct 2020 16:30:50
DataPoint Un-verified.	System	29 Oct 2020 16:30:50
User entered empty.	System	29 Oct 2020 16:30:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'Texas'	Victoria Hernandez (b) (4)	14 Oct 2020 15:28:18

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered '78229'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4)	29 Oct 2020 16:30:40
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:50:36
User entered 'US'	System	08 Oct 2020 12:03:10

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 19:03:53
User entered '5'	System	19 Apr 2021 18:37:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
User entered '4'	System	25 Nov 2020 20:02:58
User entered '3'	System	02 Nov 2020 15:57:06
User entered '2'	System	29 Oct 2020 16:30:50
User entered '1'	System	08 Oct 2020 12:03:10

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:16:48
User entered '29/Oct/2020 16:30'	System	29 Oct 2020 16:30:50

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:30:09

**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)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	23 Nov 2020 15:16:49
Reviewed for Safety.	(b) (4), (b) (6)	02 Nov 2020 15:56:50
User entered 'l'		29 Oct 2020 16:30:50

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'USA-US072-2020-MRNA-1273-P301000005'		08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Douglas'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Denham'	System	08 Oct 2020 12:02:45



US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered '7940 Floyd Curl Drive'	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:28:55
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered '5430 Fredericksburg Road, Suite 200'	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:50:36
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered '7940 Floyd Curl Drive'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'San Antonio'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered empty.	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:29:01
User closed query 'Please verify if the State should be entered and update.' (Site from CRA).		06 Nov 2020 18:28:59
Query 'Please verify if the State should be entered and update.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:18
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User opened query 'Please verify if the State should be entered and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 23:01:39
Reviewed for Safety.		02 Nov 2020 15:56:50
Un-reviewed for Safety.	System	29 Oct 2020 16:30:50
DataPoint Un-verified.	System	29 Oct 2020 16:30:50
User entered empty.	System	29 Oct 2020 16:30:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'Texas'	Victoria Hernandez (b) (4)	14 Oct 2020 15:28:18

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered '78229'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4)	29 Oct 2020 16:30:40
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:50:36
User entered 'US'	System	08 Oct 2020 12:03:10

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 19:03:53
User entered '5'	System	19 Apr 2021 18:37:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
User entered '4'	System	25 Nov 2020 20:02:58
User entered '3'	System	02 Nov 2020 15:57:06
User entered '2'	System	29 Oct 2020 16:30:50
User entered '1'	System	08 Oct 2020 12:03:10

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Nov 2020 15:16:54
User entered '02/Nov/2020 15:57'	System	02 Nov 2020 15:57:06

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:30:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	23 Nov 2020 15:16:56
User entered 'l'	(b) (4), (b) (6)	02 Nov 2020 15:57:06



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'USA-US072-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Oct 2020 19:50:36
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Douglas'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Denham'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered '7940 Floyd Curl Drive'	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:28:55
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered '5430 Fredericksburg Road, Suite 200'	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:50:36
DataPoint Verified.		
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered '7940 Floyd Curl Drive'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'San Antonio'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered empty.	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:29:01
User closed query 'Please verify if the State should be entered and update.' (Site from CRA).		06 Nov 2020 18:28:59
Query 'Please verify if the State should be entered and update.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:18
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User opened query 'Please verify if the State should be entered and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 23:01:39
Reviewed for Safety.		02 Nov 2020 15:56:50
Un-reviewed for Safety.	System	29 Oct 2020 16:30:50
DataPoint Un-verified.	System	29 Oct 2020 16:30:50
User entered empty.	System	29 Oct 2020 16:30:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'Texas'	Victoria Hernandez (b) (4)	14 Oct 2020 15:28:18

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered '78229'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'US'	System	08 Oct 2020 12:03:10

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 19:03:53
User entered '5'	System	19 Apr 2021 18:37:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
User entered '4'	System	25 Nov 2020 20:02:58
User entered '3'	System	02 Nov 2020 15:57:06
User entered '2'	System	29 Oct 2020 16:30:50
User entered '1'	System	08 Oct 2020 12:03:10



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (4)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	18 Jan 2021 19:44:20
User entered '25/Nov/2020 15:02'	System	25 Nov 2020 20:02:58

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:30:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	18 Jan 2021 19:44:20
User entered 'l'	(b) (4), (b) (6)	25 Nov 2020 20:02:58

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'USA-US072-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'		08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Douglas'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Denham'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered '7940 Floyd Curl Drive'	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:28:55
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered '5430 Fredericksburg Road, Suite 200'	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
reason for change: Data Entry Error		
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:50:36
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered '7940 Floyd Curl Drive'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'San Antonio'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered empty.	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:29:01
User closed query 'Please verify if the State should be entered and update.' (Site from CRA).		06 Nov 2020 18:28:59
Query 'Please verify if the State should be entered and update.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:18
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User opened query 'Please verify if the State should be entered and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 23:01:39
Reviewed for Safety.		02 Nov 2020 15:56:50
Un-reviewed for Safety.	System	29 Oct 2020 16:30:50
DataPoint Un-verified.	System	29 Oct 2020 16:30:50
User entered empty.	System	29 Oct 2020 16:30:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'Texas'	Victoria Hernandez (b) (4)	14 Oct 2020 15:28:18

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered '78229'		08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4)	29 Oct 2020 16:30:40
DataPoint Verified.	(b) (4), (b) (6)	21 Oct 2020 19:50:36
User entered 'US'	System	08 Oct 2020 12:03:10

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 19:03:53
User entered '5'	System	19 Apr 2021 18:37:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
User entered '4'	System	25 Nov 2020 20:02:58
User entered '3'	System	02 Nov 2020 15:57:06
User entered '2'	System	29 Oct 2020 16:30:50
User entered '1'	System	08 Oct 2020 12:03:10

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (5)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:24:33
User entered '19/Apr/2021 14:37'	System	19 Apr 2021 18:37:05

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:30:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 19:03:26
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:06
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:24:33
User entered 'l'		19 Apr 2021 18:37:05

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'USA-US072-2020-MRNA-1273-P301000005'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45



**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Yes (Y)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'No (N)'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 21 Oct 2020 19:50:36
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered 'Douglas'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'Denham'	System	08 Oct 2020 12:02:45

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered '7940 Floyd Curl Drive'	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:28:55
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered '5430 Fredericksburg Road, Suite 200'	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
reason for change: Data Entry Error	(b) (4), (b) (6)	21 Oct 2020 19:50:36
DataPoint Verified.		
Reviewed for Safety.		08 Oct 2020 12:03:04
User entered '7940 Floyd Curl Drive'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered 'San Antonio'		08 Oct 2020 12:02:45



US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

Site Address: [State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	19 Apr 2021 18:36:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4), (b) (6)	18 Jan 2021 19:44:20
DataPoint Un-verified.	System	25 Nov 2020 20:02:58
User entered empty.	System	25 Nov 2020 20:02:58
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 18:29:01
User closed query 'Please verify if the State should be entered and update.' (Site from CRA).		06 Nov 2020 18:28:59
Query 'Please verify if the State should be entered and update.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:18
Un-reviewed for Safety.	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User entered 'TEXAS' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	06 Nov 2020 18:20:09
User opened query 'Please verify if the State should be entered and update.' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 23:01:39
Reviewed for Safety.		02 Nov 2020 15:56:50
Un-reviewed for Safety.	System	29 Oct 2020 16:30:50
DataPoint Un-verified.	System	29 Oct 2020 16:30:50
User entered empty.	System	29 Oct 2020 16:30:50
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'Texas'	Victoria Hernandez (b) (4)	14 Oct 2020 15:28:18

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
DataPoint Verified.	(b) (4)	21 Oct 2020 19:50:36
Reviewed for Safety.	(b) (4), (b) (6)	08 Oct 2020 12:03:04
User entered '78229'	System	08 Oct 2020 12:02:45

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	29 Oct 2020 16:30:40
DataPoint Verified.		21 Oct 2020 19:50:36
User entered 'US'	System	08 Oct 2020 12:03:10

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:30:09

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 19:03:53
User entered '5'	System	19 Apr 2021 18:37:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
	(b) (4)	
User entered '4'	System	25 Nov 2020 20:02:58
User entered '3'	System	02 Nov 2020 15:57:06
User entered '2'	System	29 Oct 2020 16:30:50
User entered '1'	System	08 Oct 2020 12:03:10

**US3292304**

**Folder: SAE USA-US072-2020-MRNA-1273-P301000005**

**Form: Safety Report Form (6)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	03 May 2021 14:57:00
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:44
User entered '30/Apr/2021 15:03'	(b) (4) System	30 Apr 2021 19:03:53

US3292304

Folder: SAE USA-US072-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:30:09

**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)	03 May 2021 14:57:00
User signature succeeded.	Douglas Denham (b) (4)	03 May 2021 14:18:44
User entered 'I'	(b) (4), (b) (6)	30 Apr 2021 19:03:53

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'USA-US072-2021-MRNA-1273-P301000010'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Yes (Y)'	System	21 Jan 2021 17:40:38



**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Yes (Y)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Douglas'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Denham'	System	21 Jan 2021 17:40:38



**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered '7940 Floyd Curl Drive'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'San Antonio'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered '78229'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'US'	System	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 14:32:50
User entered '2'	System	19 Apr 2021 18:34:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '1'	(b) (4) System	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'USA-US072-2021-MRNA-1273-P301000010'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Yes (Y)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38



**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Yes (Y)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Douglas'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Denham'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered '7940 Floyd Curl Drive'	System	21 Jan 2021 17:40:38



**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'San Antonio'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered '78229'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'US'	System	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 14:32:50
User entered '2'	System	19 Apr 2021 18:34:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '1'	(b) (4) System	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (1)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:42
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '21/Jan/2021 12:41'	(b) (4) System	21 Jan 2021 17:41:04

US3292304

Folder: SAE USA-US072-2021-MRNA-1273-P301000010

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:30:09

**Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:42
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4)	21 Jan 2021 17:41:11
User entered 'l'	(b) (4), (b) (6)	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'USA-US072-2021-MRNA-1273-P301000010'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Yes (Y)'	System	21 Jan 2021 17:40:38



**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Yes (Y)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Douglas'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Denham'	System	21 Jan 2021 17:40:38



**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered '7940 Floyd Curl Drive'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'San Antonio'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered '78229'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'US'	System	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 14:32:50
User entered '2'	System	19 Apr 2021 18:34:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '1'	(b) (4) System	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (2)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:06
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 15:24:45
User entered '19/Apr/2021 14:34'	System	19 Apr 2021 18:34:26

US3292304

Folder: SAE USA-US072-2021-MRNA-1273-P301000010

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:30:09

**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 Apr 2021 15:51:06
Reviewed for Safety.	(b) (4)	22 Apr 2021 14:32:30
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 15:24:45
User entered 'l'		19 Apr 2021 18:34:26

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'USA-US072-2021-MRNA-1273-P301000010'	System	21 Jan 2021 17:40:38



**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

**Serious**

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Yes (Y)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Yes (Y)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'No (N)'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Douglas'	System	21 Jan 2021 17:40:38



**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'Denham'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered '7940 Floyd Curl Drive'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'San Antonio'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered '78229'	System	21 Jan 2021 17:40:38

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	09 Mar 2021 17:11:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	21 Jan 2021 17:41:11
User entered 'US'	System	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form**

**Generated On: 09 Jun 2021 16:30:09**

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Apr 2021 14:32:50
User entered '2'	System	19 Apr 2021 18:34:26
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:08:28
User entered '1'	(b) (4) System	21 Jan 2021 17:41:04

**US3292304**

**Folder: SAE USA-US072-2021-MRNA-1273-P301000010**

**Form: Safety Report Form (3)**

**Generated On: 09 Jun 2021 16:30:09**

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 19:55:39
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:06
User entered '22/Apr/2021 10:32'	(b) (4) System	22 Apr 2021 14:32:50

US3292304

Folder: SAE USA-US072-2021-MRNA-1273-P301000010

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:30:09

**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)	22 Apr 2021 19:55:39
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:06
User entered 'I'	(b) (4), (b) (6)	22 Apr 2021 14:32:50