

US3292316 (Prod: Clinical Trials of Texas, Inc)

Generated By: KC Joubran

Generated On: 09 Jun 2021 16:31:58

All time stamps listed in this document are displayed in GMT

US3292316

Form: Participant Creation

Data signed: (b) (4) 23 Feb 2021 14:11:44

Generated On: 09 Jun 2021 16:31:58

[Participant ID](#)

US3292316

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

US3292316

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Date of Birth (MMM yyyy)	(b) (6) 1980
Age	39
Age Units	YEARS
Age (Derived)	39
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input checked="" type="radio"/> Not Hispanic or Latino <input type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 23 Feb 2021 14:12:23

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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

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 23 Feb 2021 14:12:23

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	PENICILLIN ALLERGY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	BILATERAL LASIK SURGERY
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

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	VAGINAL DELIVERY
Start date (dd MMM yyyy)	UN UNK 1996
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 1996
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1996
Start Year (derived)	1996
Stop Month and Year (derived)	JAN 1996
Stop Year (derived)	1996

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	VAGINAL DELIVERY
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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	MYOPIA
Start date (dd MMM yyyy)	UN UNK 1986
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2005
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1986
Start Year (derived)	1986
Stop Month and Year (derived)	JAN 2005
Stop Year (derived)	2005

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	TONSILLITIS
Start date (dd MMM yyyy)	UN UNK 1984
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 1984
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1984
Start Year (derived)	1984
Stop Month and Year (derived)	JAN 1984
Stop Year (derived)	1984

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	ASTHMA
Start date (dd MMM yyyy)	UN UNK 1981
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 1981
Start Year (derived)	1981
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	NONALCOHOLIC FATTY LIVER DISEASE
Start date (dd MMM yyyy)	UN UNK 2006
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 2006
Start Year (derived)	2006
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	DIABETIC PERIPHERAL NEUROPATHY (HANDS AND FEET)
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	TYPE II DIABETES
Start date (dd MMM yyyy)	UN UNK 2003
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 2003
Start Year (derived)	2003
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (17)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	HYPOTHYROID
Start date (dd MMM yyyy)	UN UNK 1997
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 1997
Start Year (derived)	1997
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (18)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	SCOLIOSIS
Start date (dd MMM yyyy)	UN UNK 1985
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 1985
Start Year (derived)	1985
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (19)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (20)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	BIPOLAR I
Start date (dd MMM yyyy)	UN UNK 2017
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 2017
Start Year (derived)	2017
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (21)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	HEADACHES
Start date (dd MMM yyyy)	UN UNK 1994
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 1994
Start Year (derived)	1994
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (22)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	PTSD
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292316

Folder: Screening

Form: Medical History (23)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Condition	FACTOR II DEFICIENCY
Start date (dd MMM yyyy)	UN UNK 2001
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 2001
Start Year (derived)	2001
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3292316

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:12:23

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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)	15:00 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:00
Height (xxx.x)	169.9 cm
Weight (xxx.x)	127.5 kg
BMI (xxx.x)	44.16960 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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.

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Date of assessment (dd MMM yyyy) 25 AUG 2020

Is the participant of childbearing potential? Yes ☐
No ☒

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

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) UN UNK 2010

Date of surgery unknown False

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

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:12:23

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Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 23 Feb 2021 14:12:23

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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

What was the participant's randomization number? 144979

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

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

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

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

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

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

Liver Disease Yes ☒
 No ☐

Human Immunodeficiency Virus (HIV) infection Yes ☐
 No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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)	15:10 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 15:10
Temperature (xxx.x)	036.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	064 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	014 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	080 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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)	17:18 (24 HR)
Vital Signs Date and Time (derived)	25 AUG 2020 17:18
Temperature (xxx.x)	036.9 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	052 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	016 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	081 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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) 16:41 (24 HR)

Treatment Date and Time (derived) 25 AUG 2020 16:41

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

US3292316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

25 AUG 2020

Collection time (00:00-23:59)

15:40 (24 HR)

Collection date and time (derived)

25 AUG 2020 15:40

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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	15:59	25 AUG 2020 15:59
Nasopharyngeal Swab 2	No		

US3292316

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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

98.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 AUG 2020 17:35

PC Open Date & Time

25 AUG 2020 17:01

PC Close Date & Time

25 AUG 2020 19:31

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

97.7 °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 20:27
PC Open Date & Time	25 AUG 2020 20:26
PC Close Date & Time	26 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

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

98.1 °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

26 AUG 2020 19:23

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

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

98.2 °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

27 AUG 2020 20:07

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.8 °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 20:18

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 20:03

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 22:47

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

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

98.2 °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

31 AUG 2020 20:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 17:36

PC Open Date & Time

25 AUG 2020 17:01

PC Close Date & Time

25 AUG 2020 19:31

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 20:27

PC Open Date & Time

25 AUG 2020 20:26

PC Close Date & Time

26 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

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 19:24

PC Open Date & Time

26 AUG 2020 12:00

PC Close Date & Time

27 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

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 20:07

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

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 20:17

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

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 20:03

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 22:47

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

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 20:03

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 17:36
PC Open Date & Time	25 AUG 2020 17:01
PC Close Date & Time	25 AUG 2020 19:31

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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

No ☒

Yes ☐

PC Time stamp	25 AUG 2020 20:28
PC Open Date & Time	25 AUG 2020 20:26
PC Close Date & Time	26 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	26 AUG 2020 19:25
PC Open Date & Time	26 AUG 2020 12:00
PC Close Date & Time	27 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 20:08
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 20:18
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 20:03
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

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

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EAB) (1725)

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 22:45
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:04
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3292316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

2 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292316

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292316

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

15 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292316

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

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)	14:16 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 14:16
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	85 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

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)	15:23 (24 HR)
Vital Signs Date and Time (derived)	22 SEP 2020 15:23
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="checkbox"/>
	Axillary <input type="checkbox"/>
	Other <input type="checkbox"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	83 mmHg
Diastolic Blood Pressure units	MMHG

US3292316

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

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.

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

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) 14:52 (24 HR)

Treatment Date and Time (derived) 22 SEP 2020 14:52

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

US3292316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 SEP 2020

Collection time (00:00-23:59)

14:28 (24 HR)

Collection date and time (derived)

22 SEP 2020 14:28

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

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	14:35	22 SEP 2020 14:35
Nasopharyngeal Swab 2	No		

US3292316

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

22 SEP 2020 15:25

PC Open Date & Time

22 SEP 2020 15:12

PC Close Date & Time

22 SEP 2020 17:42

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒
No ☐

Please record your **TEMPERATURE** in °F

96.7 °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	23 SEP 2020 01:53
PC Open Date & Time	22 SEP 2020 18:37
PC Close Date & Time	23 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

99.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

23 SEP 2020 18:56

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

24 SEP 2020 23:59

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

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

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

25 SEP 2020 20:02

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

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

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 SEP 2020 22:09

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

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

94.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 SEP 2020 06:45

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °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

28 SEP 2020 20:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 15:25

PC Open Date & Time

22 SEP 2020 15:12

PC Close Date & Time

22 SEP 2020 17:42

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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

23 SEP 2020 01:53

PC Open Date & Time

22 SEP 2020 18:37

PC Close Date & Time

23 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

7

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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 18:57

PC Open Date & Time

23 SEP 2020 12:00

PC Close Date & Time

24 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

2

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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 00:00

PC Open Date & Time

24 SEP 2020 12:00

PC Close Date & Time

25 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

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 - **SWELLING/HARDNESS AT INJECTION SITE**
(in mm)

2

Measure the largest size across any injection site swelling/hardness
with the ruler provided.

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 20:04

PC Open Date & Time

25 SEP 2020 12:00

PC Close Date & Time

26 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

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 22:09

PC Open Date & Time

26 SEP 2020 12:00

PC Close Date & Time

27 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 06:45

PC Open Date & Time

27 SEP 2020 12:00

PC Close Date & Time

28 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

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

28 SEP 2020 20:03

PC Open Date & Time

28 SEP 2020 12:00

PC Close Date & Time

29 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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

No ☒

Yes ☐

PC Time stamp	22 SEP 2020 15:25
PC Open Date & Time	22 SEP 2020 15:12
PC Close Date & Time	22 SEP 2020 17:42

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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

No ☒

Yes ☐

PC Time stamp	23 SEP 2020 01:53
PC Open Date & Time	22 SEP 2020 18:37
PC Close Date & Time	23 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	23 SEP 2020 18:58
PC Open Date & Time	23 SEP 2020 12:00
PC Close Date & Time	24 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	25 SEP 2020 20:04
PC Open Date & Time	25 SEP 2020 12:00
PC Close Date & Time	26 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	26 SEP 2020 22:10
PC Open Date & Time	26 SEP 2020 12:00
PC Close Date & Time	27 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 06:46
PC Open Date & Time	27 SEP 2020 12:00
PC Close Date & Time	28 SEP 2020 11:59

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

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)

121 of 3216

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

Yes <input type="checkbox"/>	
PC Time stamp	28 SEP 2020 20:03
PC Open Date & Time	28 SEP 2020 12:00
PC Close Date & Time	29 SEP 2020 11:59

US3292316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

29 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292316

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

6 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292316

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

13 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292316

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	21 OCT 2020
Time of assessment (00:00-23:59)	09:30 (24 HR)
Vital Signs Date and Time (derived)	21 OCT 2020 09:30
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	20 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	87 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292316

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

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.

US3292316

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

21 OCT 2020

Collection time (00:00-23:59)

10:06 (24 HR)

Collection date and time (derived)

21 OCT 2020 10:06

US3292316

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:24

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 OCT 2020 15:32:20

Patient Cloud Open Date & Time

25 OCT 2020 00:01

Patient Cloud Close Date & Time

29 OCT 2020 23:59

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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	03 NOV 2020 15:37:27
Patient Cloud Open Date & Time	01 NOV 2020 00:01
Patient Cloud Close Date & Time	05 NOV 2020 23:59

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 10:02:23

Patient Cloud Open Date & Time

08 NOV 2020 00:01

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 NOV 2020 14:23:46
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 96
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 NOV 2020 15:48:52
Patient Cloud Open Date & Time	26 NOV 2020 00:01
Patient Cloud Close Date & Time	30 NOV 2020 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 00:25:58

Patient Cloud Open Date & Time

03 DEC 2020 00:01

Patient Cloud Close Date & Time

07 DEC 2020 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 03:53:39
Patient Cloud Open Date & Time	10 DEC 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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 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"/>
Have 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	17 DEC 2020 15:46:27
Patient Cloud Open Date & Time	17 DEC 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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	26 DEC 2020 12:21:26
Patient Cloud Open Date & Time	24 DEC 2020 00:01
Patient Cloud Close Date & Time	28 DEC 2020 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 DEC 2020 20:00:45

Patient Cloud Open Date & Time

31 DEC 2020 00:01

Patient Cloud Close Date & Time

04 JAN 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 138
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	08 JAN 2021 07:33:35
Patient Cloud Open Date & Time	07 JAN 2021 00:01
Patient Cloud Close Date & Time	11 JAN 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 145
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	15 JAN 2021 12:55:34
Patient Cloud Open Date & Time	14 JAN 2021 00:01
Patient Cloud Close Date & Time	18 JAN 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

21 JAN 2021 12:39:46

Patient Cloud Open Date & Time

21 JAN 2021 00:01

Patient Cloud Close Date & Time

25 JAN 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 159
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	30 JAN 2021 00:42:49
Patient Cloud Open Date & Time	28 JAN 2021 00:01
Patient Cloud Close Date & Time	01 FEB 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	04 FEB 2021 04:55:48
Patient Cloud Open Date & Time	04 FEB 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 00:04:35

Patient Cloud Open Date & Time

11 FEB 2021 00:01

Patient Cloud Close Date & Time

15 FEB 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

20 FEB 2021 05:07:47

Patient Cloud Open Date & Time

18 FEB 2021 00:01

Patient Cloud Close Date & Time

22 FEB 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 FEB 2021 20:01:35

Patient Cloud Open Date & Time

25 FEB 2021 00:01

Patient Cloud Close Date & Time

01 MAR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 MAR 2021 00:40:52

Patient Cloud Open Date & Time

04 MAR 2021 00:01

Patient Cloud Close Date & Time

08 MAR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 MAR 2021 20:00:43

Patient Cloud Open Date & Time

11 MAR 2021 00:01

Patient Cloud Close Date & Time

15 MAR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

20 MAR 2021 15:25:23

Patient Cloud Open Date & Time

18 MAR 2021 00:01

Patient Cloud Close Date & Time

22 MAR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

26 MAR 2021 14:41:50

Patient Cloud Open Date & Time

25 MAR 2021 00:01

Patient Cloud Close Date & Time

29 MAR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 01:07:32

Patient Cloud Open Date & Time

01 APR 2021 00:01

Patient Cloud Close Date & Time

05 APR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	09 APR 2021 00:32:50
Patient Cloud Open Date & Time	08 APR 2021 00:01
Patient Cloud Close Date & Time	12 APR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

15 APR 2021 07:14:09

Patient Cloud Open Date & Time

15 APR 2021 00:01

Patient Cloud Close Date & Time

19 APR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

22 APR 2021 00:01:54

Patient Cloud Open Date & Time

22 APR 2021 00:01

Patient Cloud Close Date & Time

26 APR 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

01 MAY 2021 20:05:44

Patient Cloud Open Date & Time

29 APR 2021 00:01

Patient Cloud Close Date & Time

03 MAY 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 <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	False <input type="checkbox"/>
New loss of taste	False <input type="checkbox"/>
New loss of smell	False <input type="checkbox"/>
Sore throat	False <input type="checkbox"/>
Congestion	False <input type="checkbox"/>
Runny nose	False <input type="checkbox"/>
Nausea	False <input type="checkbox"/>
Vomiting	False <input type="checkbox"/>
Diarrhea	False <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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

13 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

20 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 MAY 2021 00:01
Patient Cloud Close Date & Time	31 MAY 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

17 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

12 JUL 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 327
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

05 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 369

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

09 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 397

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

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

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

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

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

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

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

14 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

18 OCT 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

15 NOV 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

06 DEC 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

09 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

16 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

20 DEC 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

23 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

27 DEC 2021 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

30 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

06 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

13 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 516

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

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

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

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

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

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

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

20 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

03 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

10 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

17 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

21 FEB 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 FEB 2022 00:01
Patient Cloud Close Date & Time	28 FEB 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

10 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

17 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

24 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

31 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

11 APR 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

14 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

05 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

12 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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11 JUL 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

25 JUL 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

04 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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01 SEP 2022 00:01

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05 SEP 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

12 SEP 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 761

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

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

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

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

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

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

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

[Patient Cloud Open Date & Time](#)

06 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

10 OCT 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

13 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

17 OCT 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 OCT 2022 00:01

[Patient Cloud Close Date & Time](#)

24 OCT 2022 23:59

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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"/>

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	27 OCT 2022 00:01
Patient Cloud Close Date & Time	31 OCT 2022 23:59

US3292316

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 16:31:58

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		02 MAR 2021 01:02:56

US3292316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3292316

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:41:46

Generated On: 09 Jun 2021 16:31:58

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

Visit date (dd MMM yyyy)	19 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
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US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:41:46

Generated On: 09 Jun 2021 16:31:58

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) _____

US3292316

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:41:46

Generated On: 09 Jun 2021 16:31:58

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.

US3292316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:41:46

Generated On: 09 Jun 2021 16:31:58

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

19 MAR 2021

Collection time (00:00-23:59)

09:55 (24 HR)

Collection date and time (derived)

19 MAR 2021 09:55

US3292316

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:41:46

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 28 Apr 2021 13:40:25

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 28 Apr 2021 13:40:25

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3292316

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Data signed: (b) (4) 23 Feb 2021 14:12:22

Generated On: 09 Jun 2021 16:31:58

Date of Contact	14 DEC 2020
Time of Contact	15:05
Date and Time of Contact (derived)	14 DEC 2020 15:05
Type of Contact	<div>Clinic Visit - Scheduled<input type="checkbox"/></div> <div>Clinical Visit - Unscheduled<input type="checkbox"/></div> <div>Safety Call<input checked="" type="checkbox"/></div> <div>Convalescent Tele-visit<input type="checkbox"/></div>
Has the subject reported symptoms of SARS-COV-2?	<div>Yes<input checked="" type="checkbox"/></div> <div>No<input type="checkbox"/></div>

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	12 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:41:45

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	13 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Data signed: (b) (4) 16 Apr 2021 14:41:45

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	14 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	ND - Not Done
-------------	---------------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (3)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	15 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	98 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	38.2 C
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (4)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Nasal Congestion	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	16 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	95 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.2 C
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (5)

Data signed: (b) (4) 16 Apr 2021 14:41:45

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Nasal Congestion	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:41:45

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	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	17 DEC 2020	
Assessment Not Done	False	
O2 Saturation	95 %	
O2 Saturation Units	%	
Temperature	36.2 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Data signed: (b) (4) 16 Apr 2021 14:41:45

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Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	19 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	96 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.2 C
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	20 DEC 2020	
Assessment Not Done	False	
O2 Saturation	96 %	
O2 Saturation Units	%	
Temperature	36.6 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input checked="" type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	21 DEC 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	36.8 C	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (9)

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	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

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Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	18 DEC 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	94 %
---------------	------

O2 Saturation Units	%
---------------------	---

Temperature	36.9 C
-------------	--------

Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Cough	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Nasal Congestion

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Runny Nose (Rhinorrhea)

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Nausea

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

Vomiting

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Diarrhea

None ☒
Mild ☐
Moderate ☐
Severe ☐
Not Done ☐

Sore Throat

None ☐
Mild ☒
Moderate ☐
Severe ☐
Not Done ☐

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 23 Feb 2021 14:11:44

Generated On: 09 Jun 2021 16:31:58

Date of Visit 15 DEC 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 15 DEC 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 23 Feb 2021 14:12:22

Generated On: 09 Jun 2021 16:31:58

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	17 DEC 2020
Day 5	Yes	19 DEC 2020
Day 7	Yes	21 DEC 2020
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

US3292316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	15 DEC 2020
Was visit performed at the participant's home or at the clinic?	Home <input checked="" type="radio"/>
	Clinic <input type="radio"/>
Folder OID	SICKD1

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:41:45

Generated On: 09 Jun 2021 16:31:58

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	15 DEC 2020
Time of assessment (00:00-23:59)	12:32 (24 HR)
Vital Signs Date and Time (derived)	15 DEC 2020 12:32
Height (xxx.x)	165.1 cm
Weight (xxx.x)	76.24 kg
Temperature (xxx.x)	38.22 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	79 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	138 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	75 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3292316

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

15 DEC 2020

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

US3292316

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 23 Feb 2021 14:12:23

Generated On: 09 Jun 2021 16:31:58

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

15 DEC 2020

US3292316

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

Form: Visit Date

Data signed: (b) (4) 05 Mar 2021 20:52:27

Generated On: 09 Jun 2021 16:31:58

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	4 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

US3292316

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

Form: Unblinding

Data signed: (b) (4) 23 Apr 2021 18:34:55

Generated On: 09 Jun 2021 16:31:58

Date of updated informed consent (dd MMM yyyy) 4 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) 4 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 _____

US3292316

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Mar 2021 20:52:27

Generated On: 09 Jun 2021 16:31:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00-23:59)	15:50 (24 HR)
Collection date and time (derived)	4 MAR 2021 15:50

US3292316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Mar 2021 20:52:27

Generated On: 09 Jun 2021 16:31:58

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	4 MAR 2021
Collection time (00:00 - 23:59)	15:56
Collection Date and Time (derived)	4 MAR 2021 15:56

US3292316

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 23 Feb 2021 14:11:44

Generated On: 09 Jun 2021 16:31:58

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID	
Adverse event	L FOOT ABCESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	11 OCT 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	18 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID

Adverse event

SORE THROAT

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

12 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID	
Adverse event	SINUS CONGESTION
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	12 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID	USA-US072-2021-MRNA-1273-P30 1000005
Adverse event	RIGHT GLUTE ABSCESS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	3 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)	25 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	15 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

PER SUBJECT ABSCESS IS THE
SIZE OF A "SOFTBALL" AND
THERE IS POTENTIAL SHE
MIGHT REQUIRE SURGERY FOR
DRAINAGE, SHE WILL KEEP US
UPDATED.

SUBJECT CONTACTED AND
SUBJECT STATED SHE HAD
BEEN ADMITTED TO THE
HOSPITAL ON 08JAN2021 DUE
TO THIS ABSCESS BECOMING
INFECTED. SUBJECT IS STILL IN
HOSPITAL AT THIS TIME.
REQUESTING MEDICAL
RECORDS AND REPORTING SAE

SUBJECT REPORTED THAT ON
03JAN2021 A BOIL ON BUTTOCK
POPPED CREATING AND AN
ABSCESS, SAW GYNECOLOGIST
ON 06JAN2021, DR. GAVE
CEPHALEXIN 25 MG CAP 2 CAPS
PO QID. WENT TO ER,
METROPOLITAN METHODIST
ON MCCULLOUGH ON
07JAN2021 BECAUSE BOIL
BECAME LARGER AND SHE
GOT BACTRIM, IBUPROFEN,
AND TYLENOL W CODEINE.
SKIN STARTED TO PEEL AND
BLEED AND SUBJECT WENT TO
BACK ER ON 08JAN2021 AND
WAS ADMITTED.
GYNECOLOGIST CALLED

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

SUBJECT WITH RESULTS OF
CULTURE AND CULTURE
CONCLUDED THE INFECTION
WAS RESISTANT TO REGULAR
ANTIBIOTICS, SUBJECT
STOPPED ORAL ANTIBIOTICS.
REPORTING SAE AND
REQUESTING MEDICAL
RECORDS FROM THE
HOSPITAL.

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

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID	USA-US072-2021-MRNA-1273-P30 1000005
Adverse event	DIABETIC KETOACIDOSIS
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	09 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)	15 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input checked="" type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	8 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	15 JAN 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	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 DKA DISCOVERED WHILE PATIENT WAS HOSPITALIZED FOR AN ANTIBIOTIC-RESISTANT GLUTEAL ABSCESS	
Serious Adverse Event Derived (CSA Programming Field Only)	1
Medically Attended AE Derived (CSA Programming Field Only)	1
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Folder: Adverse Events

Form: Adverse Events (6)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

0

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID

Adverse event

SHORTNESS OF BREATH

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (7)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID	
Adverse event	FATIGUE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (8)

Data signed: (b) (4) 30 Apr 2021 14:50:12

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

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID	
Adverse event	RUNNY NOSE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (9)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID	
Adverse event	FEVER
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	15 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	15 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (10)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID

Adverse event

SINUS INFECTION

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

13 DEC 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

18 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (11)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

AEID

Adverse event

SEPSIS SECONDARY TO
PERINEAL ABSCESS

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

Is this event a confirmed diagnosis of Symptomatic Covid-19?

Yes ☐

No ☒

Start date (dd MMM yyyy)

08 MAR 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

25 MAR 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

Number of Days in ICU	
Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	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	PER MEDICAL RECORDS, SUBJECT DEVELOPED SEPSIS (WITHOUT SHOCK) AFTER DEVELOPING A R GLUTE ABSCESS. SHE WAS GIVEN LINEZOLID & FLAGYL AS TREATMENT.

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Folder: Adverse Events

Form: Adverse Events (12)

Data signed: (b) (4) 30 Apr 2021 14:50:12

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 23 Feb 2021 14:11:44

Generated On: 09 Jun 2021 16:31:58

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication HEADACHES

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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 1994	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication DPN

Dose per administration 1200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2015	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication LEVEMIR

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 35

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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)	7 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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 1997
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:40:24

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Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 60-100

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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)	7 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication RISPERIDONE

Prophylaxis Yes ☐
No ☒

Indication BIPOLAR

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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 2017	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 JUN 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"/>

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 0.6

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	02 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	16 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication SULFAMETHOXAZOLE-TRIMET
HOPRIM

Prophylaxis Yes ☐
No ☒

Indication LEFT FOOT ABSCESS

Dose per administration 800/160

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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)	16 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	20 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication CEFUROXIME AXETIL

Prophylaxis Yes ☐
No ☒

Indication LEFT FOOT ABSCESS

Dose per administration 250

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	21 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	30 OCT 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication INFLUENZA VACCINE

Prophylaxis Yes ☒
No ☐

Indication INFLUENZA PROPHYLAXIS

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		13 OCT 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication TYPE II DIABETES

Dose per administration 1.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication SULFAMETHOXAZOLE

Prophylaxis Yes ☐
No ☒

Indication SINUS INFECTION

Dose per administration 800-160

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	13 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication AZITHROMYCIN

Prophylaxis Yes ☐
No ☒

Indication SINUS INFECTION

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		13 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		17 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication FEVER

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		15 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication CEPHALEXIN

Prophylaxis Yes ☒
No ☐

Indication PROPHYLAXIS R GLUTE
ABSCCESS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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)	6 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	7 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication LINEZOLID

Prophylaxis Yes ☐
No ☒

Indication R GLUTE ABSCESS

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		25 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication METRONIDOZALE

Prophylaxis Yes ☐
No ☒

Indication R GLUTE ABSCESS

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)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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 type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	25 JAN 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication LANTUS

Prophylaxis Yes ☐
No ☒

Indication DIABETEC KETOACIDOSIS

Dose per administration 50

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

If dose unit is Other, specify UNIT

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DIABETIC KETOACIDOSIS

Dose per administration 22

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

If dose unit is Other, specify UNIT

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication SORE THROAT

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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)		12 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		18 DEC 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"/>

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication R GLUTE ABSCESS (SAE)

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	07 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication BACTRIM

Prophylaxis Yes ☐
No ☒

Indication R GLUTE ABSCESS (SAE)

Dose per administration 800/160

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	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)	07 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	09 JAN 2021	
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"/>	

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

Name of Medication TYLENOL W/ CODEINE

Prophylaxis Yes ☐
No ☒

Indication R GLUTE ABSCESS PAIN

Dose per administration 300/30

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 28 Apr 2021 13:40:24

Generated On: 09 Jun 2021 16:31:58

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		07 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 JAN 2021
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 23 Apr 2021 18:34:53

Generated On: 09 Jun 2021 16:31:58

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 22 Apr 2021 15:51:23

Generated On: 09 Jun 2021 16:31:58

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
08 JAN 2021	CT/ PELVIS	Adverse Event	
13 JAN 2021	CHEST XRAY	Adverse Event	
09 JAN 2021	R GLUTE ABSCESS SURGICAL DEBRIDEMENT	Adverse Event	

US3292316

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 16:31:58

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 16:31:58

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 ☐

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8
Date of submission (Pre-filled from custom function)	12/JAN/2021 19:01
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8
Date of submission (Pre-filled from custom function)	22/FEB/2021 13:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8
Date of submission (Pre-filled from custom function)	09/MAR/2021 13:20
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8
Date of submission (Pre-filled from custom function)	22/MAR/2021 10:18
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

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8
Date of submission (Pre-filled from custom function)	06/APR/2021 07:45
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

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8
Date of submission (Pre-filled from custom function)	15/APR/2021 16:00
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

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8
Date of submission (Pre-filled from custom function)	22/APR/2021 14:15
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

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 30 Apr 2021 14:50:13

Generated On: 09 Jun 2021 16:31:58

SAEID	USA-US072-2021-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)	8
Date of submission (Pre-filled from custom function)	29/APR/2021 14:10
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3292316 (Prod: Clinical Trials of Texas, Inc)

US3292316

Form: Participant Creation

Generated On: 09 Jun 2021 16:31:58

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Jan 2021 21:23:08
User entered 'US3292316'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 20:24:51

US3292316

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:12:46
User entered 'Yes (Y)'		27 Aug 2020 17:59:16

US3292316

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:12:46
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 20:24:52

US3292316

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:12:46
User entered 'Clinic (Clinic)'		27 Aug 2020 17:59:16

US3292316

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'SCRN'	System	27 Aug 2020 17:59:16

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
Query 'Please Provide source' canceled (Site from CRA).		11 Feb 2021 16:18:13
User opened query 'Please Provide source' (Site from CRA).		29 Jan 2021 17:14:04
User entered (b) (6) 1980'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 20:24:53

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered '39'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'YEARS'	System	27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '39'	System	25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'Female (F)'	(b) (4), (b) (6)	27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'Hispanic or Latino (HISPANIC OR LATINO)'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[White](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered 'l'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered '0'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered '0'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered '0'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered '0'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:18:50
User entered empty.		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:50
User entered '0'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 16:31:58

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:18:50
User entered '0'		27 Aug 2020 17:59:24

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:14:34
User entered '25 Aug 2020'		25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Aug 2020'	System	25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2020'	System	25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:14:34
User entered 'Amendment 3 (3)'		25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:14:34
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:14:34
User entered empty.		25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:14:34
User entered empty.		25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:14:34
User entered 'No (N)'		25 Aug 2020 21:44:49

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:14:34
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 20:24:52

US3292316

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 16:31:58

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'l'	System	25 Aug 2020 21:44:54

US3292316

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:14:49
User entered 'Yes (Y)'		25 Aug 2020 21:44:54

US3292316

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 16:31:58

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:18:57
Query 'Please Provide source' canceled (Site from CRA).		11 Feb 2021 16:18:55
User opened query 'Please Provide source' (Site from CRA).		29 Jan 2021 17:15:17
User entered 'Yes (Y)'		27 Aug 2020 18:10:14

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:47
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergies to foods, food additives, drugs and other chemicals, PT: Drug hypersensitivity, LLT: Penicillin allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:27
Data point term sent to Coder	System	27 Aug 2020 18:11:14
User entered 'penicillin allergy'	(b) (4), (b) (6)	27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:20:47
User entered 'un UNK 2017'		27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:47
User entered '0'		27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:47
User entered 'Yes (Y)'		27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:20:47
User entered empty.		27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	1 Feb 2021 16:20:47
User entered '0'		7 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2017'	System	27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2017'	System	27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:10:37

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:57
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Dust allergy, LLT: Dust allergy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 09:08:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	28 Aug 2020 09:08:42
Data point term sent to Coder	System	27 Aug 2020 18:11:17
User entered 'environmental dust allergy'	(b) (4), (b) (6)	27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:57
User entered 'un UNK 2018'		27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:57
User entered '0'		27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:57
User entered 'Yes (Y)'		27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:57
User entered empty.		27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:57
User entered '0'		27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2018'	System	27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2018'	System	27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:10:54

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:01
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Allergic conditions NEC, PT: Allergy to animal, LLT: Allergy to animal dander - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:28
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 19:46:28
Data point term sent to Coder	System	27 Aug 2020 18:11:18
User entered 'pet dander allergy'	(b) (4), (b) (6)	27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:01
User entered 'un UNK 2018'		27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:01
User entered '0'		27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:01
User entered 'Yes (Y)'		27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:01
User entered empty.		27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:01
User entered '0'		27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2018'	System	27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2018'	System	27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:11:08

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:25:36
User closed query 'Please update condition in mHx source' (Site from CRA).	(b) (4)	08 Apr 2021 19:25:27
Query 'Please update condition in mHx source' answered with 'updated in source' (Site from CRA).	Antonio Gutierrez (b) (4)	08 Mar 2021 19:14:16
User opened query 'Please update condition in mHx source' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:20:25
User closed query 'Per DM CLR: Please specify the location (bilateral, left or right eye) of LASIK SURGERY. 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 14:35:16
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:21:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 21:21:44
Data point term sent to Coder	System	22 Sep 2020 21:21:04
Query 'Per DM CLR: Please specify the location (bilateral, left or right eye) of LASIK SURGERY. 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) (b) (4)	22 Sep 2020 21:20:41
Coding entries removed.	Dawn Killian (b) (4) (b) (4)	22 Sep 2020 21:20:36
User entered 'bilateral LASIK SURGERY' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	22 Sep 2020 21:20:36
User opened query 'Per DM CLR: Please specify the location (bilateral, left or right eye) of LASIK SURGERY. 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)	09 Sep 2020 16:39:27

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Surgical and medical procedures, HLGT: Eye therapeutic procedures, HLT: Corneal and scleral therapeutic procedures, PT: Keratomileusis, LLT: LASIK eye surgery - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:33
Data point term sent to Coder	System	27 Aug 2020 18:12:19
User entered 'lasik surgery'	(b) (4), (b) (6)	27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:32
User entered 'un UNK 2005'		27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:33
User entered '0'		27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:35
User entered 'No (N)'		27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:36
User entered 'un UNK 2005'		27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:20:38
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2005'	System	27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2005'	System	27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2005'	System	27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2005'	System	27 Aug 2020 18:11:30

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:23
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Obstetric therapeutic procedures, PT: Caesarean section, LLT: C-section - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:32
Data point term sent to Coder	System	27 Aug 2020 18:12:19
User entered 'c-section'	(b) (4), (b) (6)	27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:21:23
User entered 'un UNK 2010'		7 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:23
User entered '0'		27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:23
User entered 'No (N)'		27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:21:23
User entered 'un UNK 2010'		27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:23
User entered '0'		27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2010'	System	27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

Start Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2010'	System	27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2010'	System	27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2010'	System	27 Aug 2020 18:11:46

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:44
User coded data point as SOC: Surgical and medical procedures, HLG: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:33
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:33
Data point term sent to Coder	System	27 Aug 2020 18:12:19
User entered 'tonsillectomy'	(b) (4), (b) (6)	27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:44
User entered 'un UNK 1984'		27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:44
User entered '0'		27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:44
User entered 'No (N)'		27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:44
User entered 'un UNK 1984'		27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:44
User entered '0'		27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1984'	System	27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1984'	System	27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1984'	System	27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1984'	System	27 Aug 2020 18:12:02

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:53
User coded data point as SOC: Surgical and medical procedures, HLGT: Obstetric and gynaecological therapeutic procedures, HLT: Contraceptive methods female, PT: Female sterilisation, LLT: Tubal ligation - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:38
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 19:46:38
Data point term sent to Coder	System	27 Aug 2020 18:13:21
User entered 'tubal ligation (bilateral)'	(b) (4), (b) (6)	27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:53
User entered 'un UNK 2010'		27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:53
User entered '0'		27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:53
User entered 'No (N)'		27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:53
User entered 'un UNK 2010'		27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:21:53
User entered '0'		27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2010'	System	27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2010'	System	27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2010'	System	27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2010'	System	27 Aug 2020 18:12:22

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:00
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Delivery, LLT: Vaginal delivery - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:38
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 19:46:38
Data point term sent to Coder	System	27 Aug 2020 18:13:21
User entered 'vaginal delivery'	(b) (4), (b) (6)	27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:00
User entered 'un UNK 1996'		27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:00
User entered '0'		27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:00
User entered 'No (N)'		27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:00
User entered 'un UNK 1996'		27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:00
User entered '0'		27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1996'	System	27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1996'	System	27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1996'	System	27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1996'	System	27 Aug 2020 18:12:39

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:01
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Delivery, LLT: Vaginal delivery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:39
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 19:46:39
Data point term sent to Coder	System	27 Aug 2020 18:13:24
User entered 'vaginal delivery'	(b) (4), (b) (6)	27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:01
User entered 'un UNK 2000'		27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:01
User entered '0'		27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 16:22:01
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:01
User entered 'un UNK 2000'		27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 16:22:01
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2000'	System	27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2000'	System	27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2000'	System	27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2000'	System	27 Aug 2020 18:12:53

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:03
User coded data point as SOC: Pregnancy, puerperium and perinatal conditions, HLGT: Pregnancy, labour, delivery and postpartum conditions, HLT: Normal pregnancy, labour and delivery, PT: Delivery, LLT: Vaginal delivery - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:39
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 19:46:39
Data point term sent to Coder	System	27 Aug 2020 18:13:24
User entered 'vaginal delivery'	(b) (4), (b) (6)	27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:03
User entered 'un UNK 2003'		27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:22:03
User entered '0'		27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:03
User entered 'No (N)'		27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:03
User entered 'un UNK 2003'		27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:22:03
User entered '0'		27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2003'	System	27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2003'	System	27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2003'	System	27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2003'	System	27 Aug 2020 18:13:10

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:49
User coded data point as SOC: Eye disorders, HLGT: Vision disorders, HLT: Refractive and accommodative disorders, PT: Myopia, LLT: Myopia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:46
Data point term sent to Coder	System	27 Aug 2020 18:14:26
User entered 'myopia'	(b) (4), (b) (6)	27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:49
User entered 'un UNK 1986'		27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:49
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:49
User entered 'No (N)'		27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:49
User entered 'un UNK 2005'		27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:49
User entered '0'		27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1986'	System	27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1986'	System	27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2005'	System	27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2005'	System	27 Aug 2020 18:13:25

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:22
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Tonsillitis, LLT: Tonsillitis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:44
Data point term sent to Coder	System	27 Aug 2020 18:14:27
User entered 'tonsillitis'	(b) (4), (b) (6)	27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:22
User entered 'un UNK 1984'		27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:22
User entered '0'		27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 16:22:22
User entered 'No (N)'	(b) (4), (b) (6)	7 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:22
User entered 'un UNK 1984'		27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:22:22
User entered '0'		27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1984'	System	27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1984'	System	27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1984'	System	27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1984'	System	27 Aug 2020 18:13:42

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:23:10
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).		15 Oct 2020 21:43:40
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' answered with 'no treatment per subject' (Site from DM).	Dawn Killian (b) (4) (b) (4)	22 Sep 2020 21:21:21
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this condition and treatment would be expected for this condition. Please review and if applicable add a Con Med or provide an explanation for no medical treatment. ' (Site from DM).	(b) (4), (b) (6)	09 Sep 2020 16:46:29
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Bronchial disorders (excl neoplasms), HLT: Bronchospasm and obstruction, PT: Asthma, LLT: Asthma - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:45
Data point term sent to Coder	System	27 Aug 2020 18:14:27
User entered 'asthma'	(b) (4), (b) (6)	27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:23:10
User entered 'un UNK 1981'		27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:23:10
User entered '0'		27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:23:10
User entered 'Yes (Y)'		27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:23:10
User entered empty.		27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:23:10
User entered '0'		27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1981'	System	27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1981'	System	27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:13:53

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 19:27:30
User closed query 'Please update Condition in Mhx source.' (Site from CRA).		08 Apr 2021 19:27:28
Query 'Please update Condition in Mhx source.' answered with 'source updated' (Site from CRA).	Antonio Gutierrez (b) (4)	08 Mar 2021 19:16:04
User opened query 'Please update Condition in Mhx source.' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 16:23:55
User closed query 'Per MM, please spell out abbreviation.' (Site from DM).		25 Nov 2020 10:40:37
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Nonalcoholic fatty liver disease, LLT: Nonalcoholic fatty liver disease - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 19:06:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	20 Oct 2020 19:06:00
Query 'Per MM, please spell out abbreviation.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4)	20 Oct 2020 19:03:56
Data point term sent to Coder	System	20 Oct 2020 19:03:52
Coding entries removed.	Dawn Killian (b) (4)	20 Oct 2020 19:03:50
	(b) (4)	
User entered 'Nonalcoholic fatty liver disease' reason for change: Data Entry Error	Dawn Killian (b) (4)	20 Oct 2020 19:03:50
User opened query 'Per MM, please spell out abbreviation.' (Site from DM).	(b) (4)	
	(b) (4), (b) (6)	16 Oct 2020 18:47:31
User coded data point as SOC: Hepatobiliary disorders, HLGT: Hepatic and hepatobiliary disorders, HLT: Hepatocellular damage and hepatitis NEC, PT: Non-alcoholic steatohepatitis, LLT: Non-alcoholic steatohepatitis - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:46
Data point term sent to Coder	System	27 Aug 2020 18:14:28

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
User entered 'NASH'	(b) (4), (b) (6)	27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:23:59
User entered 'un UNK 2006'		27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:01
User entered '0'		27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:02
User entered 'Yes (Y)'		27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:04
User entered empty.		27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 16:24:06
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2006'	System	27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2006'	System	27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:14:10

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:19
User closed query 'Per DM CLR: Please verify the type of the DIABETIC PERIPHERAL NEUROPATHY (i.e. sensory or motor). 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).		08 Oct 2020 14:35:52
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:45:51
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Sep 2020 23:45:51
Data point term sent to Coder	System	22 Sep 2020 21:23:06
Query 'Per DM CLR: Please verify the type of the DIABETIC PERIPHERAL NEUROPATHY (i.e. sensory or motor). 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) (b) (4)	22 Sep 2020 21:22:19
Coding entries removed.	Dawn Killian (b) (4) (b) (4)	22 Sep 2020 21:22:14
User entered 'DIABETIC PERIPHERAL NEUROPATHY (hands and feet)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	22 Sep 2020 21:22:14
User opened query 'Per DM CLR: Please verify the type of the DIABETIC PERIPHERAL NEUROPATHY (i.e. sensory or motor). 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)	09 Sep 2020 16:49:03

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic peripheral neuropathy - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:53
Data point term sent to Coder	System	27 Aug 2020 18:15:29
User entered 'diabetic peripheral neuropathy'	(b) (4), (b) (6)	27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:19
User entered 'un UNK 2015'		27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:19
User entered '0'		27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:19
User entered 'Yes (Y)'		27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:19
User entered empty.		27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 16:24:19
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2015'	System	27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2015'	System	27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:14:35

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:23
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:55
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 19:46:55
Data point term sent to Coder	System	27 Aug 2020 18:15:30
User entered 'type II diabetes'	(b) (4), (b) (6)	27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:23
User entered 'un UNK 2003'		27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:23
User entered '0'		27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:23
User entered 'Yes (Y)'		27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:23
User entered empty.		27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:23
User entered '0'		27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2003'	System	27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2003'	System	27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:14:46

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:31
User coded data point as SOC: Endocrine disorders, HLGT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:54
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 19:46:54
Data point term sent to Coder	System	27 Aug 2020 18:15:30
User entered 'hypothyroid'	(b) (4), (b) (6)	27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 16:24:31
User entered 'un UNK 1997'	(b) (4), (b) (6)	27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:31
User entered '0'		27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:31
User entered 'Yes (Y)'		27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:31
User entered empty.		27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:31
User entered '0'		27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1997'	System	27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1997'	System	27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (17)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:15:05

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:41
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue deformities (incl intervertebral disc disorders), HLT: Spine and neck deformities, PT: Scoliosis, LLT: Scoliosis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:52
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 19:46:52
Data point term sent to Coder	System	27 Aug 2020 18:15:31
User entered 'scoliosis'	(b) (4), (b) (6)	27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:41
User entered 'un UNK 1985'		27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:24:41
User entered '0'		27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:41
User entered 'Yes (Y)'		27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:41
User entered empty.		27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:41
User entered '0'		27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1985'	System	27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1985'	System	27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (18)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:15:16

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:52
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:59
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 19:46:59
Data point term sent to Coder	System	27 Aug 2020 18:16:33
User entered 'anxiety'	(b) (4), (b) (6)	27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	1 Feb 2021 16:24:52
User entered 'un UNK 2017'		7 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:52
User entered '0'		27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:52
User entered 'Yes (Y)'		27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:52
User entered empty.		27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:52
User entered '0'		27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2017'	System	27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2017'	System	27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (19)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:15:35

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:54
User coded data point as SOC: Psychiatric disorders, HLGT: Manic and bipolar mood disorders and disturbances, HLT: Bipolar disorders, PT: Bipolar I disorder, LLT: Bipolar I disorder - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:46:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:46:58
Data point term sent to Coder	System	27 Aug 2020 18:16:33
User entered 'bipolar I'	(b) (4), (b) (6)	27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:54
User entered 'un UNK 2017'		27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:54
User entered '0'		27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:54
User entered 'Yes (Y)'		27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:54
User entered empty.		27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:24:54
User entered '0'		27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2017'	System	27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2017'	System	27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (20)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:15:47

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:07
User coded data point as SOC: Nervous system disorders, HLGT: Headaches, HLT: Headaches NEC, PT: Headache, LLT: Headache - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:47:02
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 19:47:02
Data point term sent to Coder	System	27 Aug 2020 18:17:36
User entered 'headaches'	(b) (4), (b) (6)	27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:07
User entered 'un UNK 1994'		27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:07
User entered '0'		27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 11 Feb 2021 16:25:07
User entered 'Yes (Y)'		27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:07
User entered empty.		27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	1 Feb 2021 16:25:07
User entered '0'		7 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1994'	System	27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1994'	System	27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (21)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:16:50

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:08
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Stress disorders, PT: Post-traumatic stress disorder, LLT: Post-traumatic stress disorder - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:47:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	27 Aug 2020 19:47:01
Data point term sent to Coder	System	27 Aug 2020 18:17:36
User entered 'PTSD'	(b) (4), (b) (6)	27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:08
User entered 'un UNK 1995'		27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:08
User entered '0'		27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:08
User entered 'Yes (Y)'		27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:08
User entered empty.		27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	1 Feb 2021 16:25:08
User entered '0'		7 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 1995'	System	27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '1995'	System	27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (22)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:17:09

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 16:25:10
User closed query 'Per MM: Please confirm if the subject did not meet EC#8 (Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy). If met, please report as possible protocol deviation.	(b) (4), (b) (6)	02 Nov 2020 13:37:49
' (Site from DM).		
Query 'Per MM: Please confirm if the subject did not meet EC#8 (Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy). If met, please report as possible protocol deviation.	Dawn Killian (b) (4)	22 Sep 2020 21:23:43
' answered with 'subject did not' (Site from DM).	(b) (4)	
User opened query 'Per MM: Please confirm if the subject did not meet EC#8 (Bleeding disorder considered a contraindication to intramuscular injection or phlebotomy). If met, please report as possible protocol deviation.	(b) (4), (b) (6)	17 Sep 2020 12:29:48
' (Site from DM).		
User coded data point as SOC: Congenital, familial and genetic disorders, HLGT: Blood and lymphatic system disorders congenital, HLT: Coagulation disorders congenital, PT: Factor II deficiency, LLT: Factor II deficiency - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:47:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	27 Aug 2020 19:47:02
Data point term sent to Coder	System	27 Aug 2020 18:17:39
User entered 'factor II deficiency'	(b) (4), (b) (6)	27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:10
User entered 'un UNK 2001'		27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:10
User entered '0'		27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:10
User entered 'Yes (Y)'		27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:10
User entered empty.		27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:25:10
User entered '0'		27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'Jan 2001'	System	27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '2001'	System	27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Medical History (23)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	27 Aug 2020 18:17:30

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 29 Jan 2021 17:15:59
User entered 'Yes (Y)'		27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:15:59
User entered '25 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:15:59
User entered '15:00'	(b) (4), (b) (6)	27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '25 Aug 2020 15:00'	System	27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 29 Jan 2021 17:15:59
User entered '169.9' cm		27 Aug 2020 18:18:50
DataPoint set to visible.	System	25 Aug 2020 21:44:54

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 29 Jan 2021 17:15:59
User entered '127.5' kg		27 Aug 2020 18:18:50
DataPoint set to visible.	System	25 Aug 2020 21:44:54

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
Amendment Manager: User entered '44.16960'	System	17 Sep 2020 00:02:42
User entered '44.2'	System	27 Aug 2020 18:18:50
DataPoint set to visible.	System	25 Aug 2020 21:44:54

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'kg/m2'	System	27 Aug 2020 18:18:50
DataPoint set to visible.	System	25 Aug 2020 21:44:54

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:15:59
User closed query 'Per CDM: As per CCG, "Not Done" to be updated in the text field. ' (Site from DM).		27 Jan 2021 12:14:48
Query 'Per CDM: As per CCG, "Not Done" to be updated in the text field. ' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	25 Jan 2021 19:08:46
User entered missing code ND - Not Done; reason for change Data Entry Error	Dawn Killian (b) (4) (b) (4)	25 Jan 2021 19:08:41
User opened query 'Per CDM: As per CCG, "Not Done" to be updated in the text field. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 08:49:58
User closed query 'Data is required. Please provide.' (Site from System).		30 Dec 2020 19:34:44
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).		30 Dec 2020 17:58:08
User opened query 'Data is required. Please provide.' System (Site from System).		30 Dec 2020 17:57:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:57:54
User entered missing code ND - Not Done.		27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:15:59
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).		23 Dec 2020 13:38:15
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) (b) (4)	21 Dec 2020 19:49:08
User entered empty; reason for change Data Entry Error	Dawn Killian (b) (4) (b) (4)	21 Dec 2020 19:49:04
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 17:23:19
User entered 'Other (Other)'	(b) (4), (b) (6)	27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:15:59
User closed query 'Per CDM: Please remove the data as this field should be "blank". ' (Site from DM).		30 Dec 2020 19:34:41
Query 'Per CDM: Please remove the data as this field should be "blank". ' answered with 'Completed' (Site from DM).		30 Dec 2020 17:58:15
User entered empty; reason for change Data Entry Error		30 Dec 2020 17:57:54
User opened query 'Per CDM: Please remove the data as this field should be "blank". ' (Site from DM).		23 Dec 2020 13:38:12
User entered missing code ND - Not Done.		27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Pulse (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:15:59
User closed query 'Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done THEN Units should be left blank.' (Site from DM).		31 Dec 2020 19:27:22
Query 'Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done THEN Units should be left blank.'	Kevin Martinez (b) (4) (b) (4)	31 Dec 2020 17:41:29
answered with 'done' (Site from DM).		
User entered missing code ND - Not Done; reason for change Data Entry Error	Kevin Martinez (b) (4) (b) (4)	31 Dec 2020 17:41:24
User opened query 'Per CDM: If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done THEN Units should be left blank.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 22:26:47
User closed query 'Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' (Site from DM).		30 Dec 2020 22:26:47
Query 'Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' answered with 'Previous queries stated to leave blank. Please advise.' (Site from DM).		30 Dec 2020 19:37:05
User opened query 'Per CDM: Response noted. If participant was Screened and Dose on same day. Pulse, Respiratory Rate, Systolic and Diastolic Blood Pressure should be recorded as Not Done. please update fields.' (Site from DM).		30 Dec 2020 19:36:42
User closed query 'Data is required. Please provide.' (Site from System).		30 Dec 2020 19:34:51

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 17:58:19
User opened query 'Data is required. Please provide.' (Site from System).	System	30 Dec 2020 17:57:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:57:54
User entered missing code ND - Not Done.		27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'bpm'	System	31 Dec 2020 17:41:24
User entered empty.	System	30 Dec 2020 17:57:54
User entered 'bpm'	System	27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:15:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Kevin Martinez (b) (4)	31 Dec 2020 17:41:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:36:45
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).		30 Dec 2020 17:58:22
User opened query 'Data is required. Please provide.' System (Site from System).		30 Dec 2020 17:57:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:57:54
User entered missing code ND - Not Done.		27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'breaths/min'	System	31 Dec 2020 17:41:24
User entered empty.	System	30 Dec 2020 17:57:54
User entered 'breaths/min'	System	27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:15:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Kevin Martinez (b) (4)	31 Dec 2020 17:41:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4)	30 Dec 2020 19:36:48
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).	(b) (4), (b) (6)	30 Dec 2020 17:58:26
User opened query 'Data is required. Please provide.' System (Site from System).		30 Dec 2020 17:57:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:57:54
User entered missing code ND - Not Done.		27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'mmHg'	System	31 Dec 2020 17:41:24
User entered empty.	System	30 Dec 2020 17:57:54
User entered 'mmHg'	System	27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:15:59
User entered missing code ND - Not Done; reason for change Data Entry Error	Kevin Martinez (b) (4)	31 Dec 2020 17:41:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	30 Dec 2020 19:36:49
Query 'Data is required. Please provide.' answered with 'Not Done' (Site from System).		30 Dec 2020 17:58:30
User opened query 'Data is required. Please provide.' System (Site from System).		30 Dec 2020 17:57:54
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	30 Dec 2020 17:57:54
User entered missing code ND - Not Done.		27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'mmHg'	System	31 Dec 2020 17:41:24
User entered empty.	System	30 Dec 2020 17:57:54
User entered 'mmHg'	System	27 Aug 2020 18:18:50

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44

US3292316

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44

US3292316

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:23
User entered 'Yes (Y)'		27 Aug 2020 18:19:16

US3292316

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:23
User entered '25 Aug 2020'		27 Aug 2020 18:19:16

US3292316

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:31:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:39
User entered '25 Aug 2020'		27 Aug 2020 18:20:40

US3292316

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:31:58

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:39
User entered 'No (N)'		27 Aug 2020 18:20:40

US3292316

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:31:58

[If No, what is the reason?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:39
User entered 'Surgically sterile (SURGICALLY STERILE)'		27 Aug 2020 18:20:40

US3292316

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:31:58

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:39
User entered empty.		27 Aug 2020 18:20:40

US3292316

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:39
User entered 'UN UNK 2010'		27 Aug 2020 18:20:40

US3292316

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:31:58

Date of surgery unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:39
User entered '0'		27 Aug 2020 18:20:40

US3292316

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:39
User entered empty.		27 Aug 2020 18:20:40

US3292316

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 16:31:58

Date of last menstruation unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:39
User entered '0'		27 Aug 2020 18:20:40

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		7 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'Yes (Y)'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'No (N)'		27 Aug 2020 18:21:39

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered empty.		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered '0'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered '0'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered '0'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:16:59
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

[Resides in a single family home \(i.e., detached housing\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered 'l'		27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '0'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:21:39

US3292316

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 16:31:58

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:16:59
User entered empty.		27 Aug 2020 18:21:39

US3292316

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:17:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:27:17

US3292316

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:06
User entered '25 Aug 2020'		27 Aug 2020 18:27:17

US3292316

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:06
User entered 'Clinic (Clinic)'		27 Aug 2020 18:27:17

US3292316

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'VISIT1'	System	27 Aug 2020 18:27:17

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:30
User entered '25 AUG 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 21:34:15

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:30
User entered '144979'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 21:34:15

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:30
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	25 Aug 2020 21:34:15

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 17:17:30
User entered 'Yes (Y)'		27 Aug 2020 18:27:44

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:17:30
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:27:44

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

Severe obesity (body mass index > or = 40kg/m2)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:30
User entered 'Yes (Y)'		27 Aug 2020 18:27:44

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:30
User entered 'Yes (Y)'		27 Aug 2020 18:27:44

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:17:30
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:27:44

US3292316

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 16:31:58

Human Immunodeficiency Virus (HIV) infection

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:30
User closed query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).		11 Dec 2020 15:29:12
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 23:18:33
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	07 Dec 2020 23:18:29
User opened query 'Per CDM: This field requires a Yes or No response. Please complete.' (Site from DM).	(b) (4), (b) (6)	01 Dec 2020 22:36:03
Amendment Manager: DataPoint set to visible.	System	19 Sep 2020 07:55:45
Amendment Manager inserted this DataPoint.	System	19 Sep 2020 07:55:44

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:31:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:37
User entered missing code ND - Not Done.		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:31:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:39
User entered missing code ND - Not Done.		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:31:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:37
User entered missing code ND - Not Done.		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:31:58

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:39
User entered missing code ND - Not Done.		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User accepted default value 'Pre-Dose (PREDOSE)'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered 'Yes (Y)'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered '25 Aug 2020'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered '15:10'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '25 Aug 2020 15:10'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered '036.2' C		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:21
User entered 'Oral (Oral)'	(b) (4), (b) (6)	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered empty.		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered '064'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'bpm'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered '014'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'breaths/min'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 29 Jan 2021 17:18:21
User entered '110'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'mmHg'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 29 Jan 2021 17:18:21
User entered '080'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'mmHg'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:31:58

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:37
User entered missing code ND - Not Done.		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 16:31:58

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:17:39
User entered missing code ND - Not Done.		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User accepted default value 'Post-Dose (POSTDOSE)'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered 'Yes (Y)'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:21
User entered '25 Aug 2020'	(b) (4), (b) (6)	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:21
User entered '17:18'	(b) (4), (b) (6)	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '25 Aug 2020 17:18'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:21
User entered '036.9' C	(b) (4), (b) (6)	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered 'Oral (Oral)'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:21
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered '052'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'bpm'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 29 Jan 2021 17:18:21
User entered '016'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'breaths/min'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:21
User entered '115'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'mmHg'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 29 Jan 2021 17:18:21
User entered '081'		27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'mmHg'	System	27 Aug 2020 18:28:57

US3292316

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:31
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:29:03

US3292316

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:31
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:29:03

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:45
User entered 'Yes (Y)'		25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:45
User entered empty.		25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:45
User entered empty.	(b) (4), (b) (6)	25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'MRNA-1273 OR PLACEBO'	System	25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:45
User entered '25 Aug 2020'		25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:18:45
User entered '16:41'		25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '25 Aug 2020 16:41'	System	25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:18:45
User entered 'Right Arm (RIGHT ARM)'	(b) (4), (b) (6)	25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
DataPoint Verified.		29 Jan 2021 17:18:45
User entered 'ONCE'	System	25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'INTRAMUSCULAR'	System	25 Aug 2020 21:45:17

US3292316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:19:40
User entered 'Yes (Y)'		27 Aug 2020 18:29:27

US3292316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:19:40
User entered '25 Aug 2020'		27 Aug 2020 18:29:27

US3292316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:19:40
User entered '15:40'		27 Aug 2020 18:29:27

US3292316

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '25 Aug 2020 15:40'	System	27 Aug 2020 18:29:27

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:31:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:19:47
User entered '25 Aug 2020'		27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:31:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:19:47
User entered 'Yes (Y)'		27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:31:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:19:47
User entered '15:59'		27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:31:58

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '25 Aug 2020 15:59'	System	27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:31:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	(b) (4), (b) (6)	27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:19:47
User entered 'No (N)'		27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:31:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:19:47
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:31:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered empty.	System	27 Aug 2020 18:29:44

US3292316

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	29 Jan 2021 17:19:52
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:29:48

US3292316

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'I'	System	27 Aug 2020 18:29:48

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:35:13', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '274740ac-c7a9-4e3f-aa63-bf1823b94e2c'	System	25 Aug 2020 22:35:37
User entered 'Yes (Y)'	System	25 Aug 2020 22:35:37

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:35:17', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '274740ac-c7a9-4e3f-aa63-bf1823b94e2c'	System	25 Aug 2020 22:35:37
User entered '98.5'	System	25 Aug 2020 22:35:37

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:35:24', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '274740ac-c7a9-4e3f-aa63-bf1823b94e2c'	System	25 Aug 2020 22:35:37
User entered 'No (N)'	System	25 Aug 2020 22:35:37

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:35:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '274740ac-c7a9-4e3f-aa63-bf1823b94e2c'	System	25 Aug 2020 22:35:37
User entered '25 Aug 2020 17:35'	System	25 Aug 2020 22:35:37

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 17:01'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 19:31'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:26:49', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a07ce6a5-a052-4b8b-8792-e227a9868f2a'	System	26 Aug 2020 01:27:07
User entered 'Yes (Y)'	System	26 Aug 2020 01:27:07

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:26:53', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a07ce6a5-a052-4b8b-8792-e227a9868f2a'	System	26 Aug 2020 01:27:07
User entered '97.7'	System	26 Aug 2020 01:27:07

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:26:57', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a07ce6a5-a052-4b8b-8792-e227a9868f2a'	System	26 Aug 2020 01:27:07
User entered 'No (N)'	System	26 Aug 2020 01:27:07

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:01', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a07ce6a5-a052-4b8b-8792-e227a9868f2a'	System	26 Aug 2020 01:27:07
User entered '25 Aug 2020 20:27'	System	26 Aug 2020 01:27:07

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 20:26'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 2'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:23:34', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a7a749e9-3b10-4ac4-86b6-7485b7e1b0cd'	System	27 Aug 2020 00:23:53
User entered 'Yes (Y)'	System	27 Aug 2020 00:23:53

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:23:38', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a7a749e9-3b10-4ac4-86b6-7485b7e1b0cd' User entered '98.1'	System	27 Aug 2020 00:23:53
	System	27 Aug 2020 00:23:53

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:23:42', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a7a749e9-3b10-4ac4-86b6-7485b7e1b0cd'	System	27 Aug 2020 00:23:53
User entered 'No (N)'	System	27 Aug 2020 00:23:53

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:23:47', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a7a749e9-3b10-4ac4-86b6-7485b7e1b0cd'	System	27 Aug 2020 00:23:53
User entered '26 Aug 2020 19:23'	System	27 Aug 2020 00:23:53

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 3'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:26', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '1b90e5c3-2f39-41b7-8be8-60fc90d77d9c'	System	28 Aug 2020 01:07:40
User entered 'Yes (Y)'	System	28 Aug 2020 01:07:40

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:29', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '1b90e5c3-2f39-41b7-8be8-60fc90d77d9c'	System	28 Aug 2020 01:07:40
User entered '98.2'	System	28 Aug 2020 01:07:40

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '1b90e5c3-2f39-41b7-8be8-60fc90d77d9c'	System	28 Aug 2020 01:07:40
User entered 'No (N)'	System	28 Aug 2020 01:07:40

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:35', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '1b90e5c3-2f39-41b7-8be8-60fc90d77d9c'	System	28 Aug 2020 01:07:40
User entered '27 Aug 2020 20:07'	System	28 Aug 2020 01:07:40

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 4'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2a15dfe9-771c-4fa1-87a5-65c35922bc35'	System	29 Aug 2020 01:18:13
User entered 'Yes (Y)'	System	29 Aug 2020 01:18:13

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:04', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2a15dfe9-771c-4fa1-87a5-65c35922bc35'	System	29 Aug 2020 01:18:13
User entered '96.8'	System	29 Aug 2020 01:18:13

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:06', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2a15dfe9-771c-4fa1-87a5-65c35922bc35'	System	29 Aug 2020 01:18:13
User entered 'No (N)'	System	29 Aug 2020 01:18:13

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:09', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2a15dfe9-771c-4fa1-87a5-65c35922bc35'	System	29 Aug 2020 01:18:13
User entered '28 Aug 2020 20:18'	System	29 Aug 2020 01:18:13

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 5'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:02:53', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd48b3b2c-49f5-448d-b28d-284120a658f2'	System	30 Aug 2020 01:03:08
User entered 'Yes (Y)'	System	30 Aug 2020 01:03:08

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:02:57', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd48b3b2c-49f5-448d-b28d-284120a658f2'	System	30 Aug 2020 01:03:08
User entered '97.6'	System	30 Aug 2020 01:03:08

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd48b3b2c-49f5-448d-b28d-284120a658f2'	System	30 Aug 2020 01:03:08
User entered 'No (N)'	System	30 Aug 2020 01:03:08

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:03', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd48b3b2c-49f5-448d-b28d-284120a658f2'	System	30 Aug 2020 01:03:08
User entered '29 Aug 2020 20:03'	System	30 Aug 2020 01:03:08

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 6'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:35', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'c0ec9747-80e7-41cf-9c08-53aba222bc57'	System	31 Aug 2020 03:47:50
User entered 'Yes (Y)'	System	31 Aug 2020 03:47:50

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'c0ec9747-80e7-41cf-9c08-53aba222bc57'	System	31 Aug 2020 03:47:50
User entered '97.4'	System	31 Aug 2020 03:47:50

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:43', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'c0ec9747-80e7-41cf-9c08-53aba222bc57'	System	31 Aug 2020 03:47:50
User entered 'No (N)'	System	31 Aug 2020 03:47:50

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:46', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'c0ec9747-80e7-41cf-9c08-53aba222bc57'	System	31 Aug 2020 03:47:50
User entered '30 Aug 2020 22:47'	System	31 Aug 2020 03:47:50

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 7'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:12', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '33ab8fa0-3ba6-4254-a3a0-dea157d0cdb6'	System	01 Sep 2020 01:03:24
User entered 'Yes (Y)'	System	01 Sep 2020 01:03:24

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '33ab8fa0-3ba6-4254-a3a0-dea157d0cdb6'	System	01 Sep 2020 01:03:24
User entered '98.2'	System	01 Sep 2020 01:03:24

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '33ab8fa0-3ba6-4254-a3a0-dea157d0cdb6'	System	01 Sep 2020 01:03:24
User entered 'No (N)'	System	01 Sep 2020 01:03:24

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '33ab8fa0-3ba6-4254-a3a0-dea157d0cdb6'	System	01 Sep 2020 01:03:24
User entered '31 Aug 2020 20:03'	System	01 Sep 2020 01:03:24

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:35:41', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bb408f61-a179-4715-9ff1-058cb2277402'	System	25 Aug 2020 22:36:14
User entered 'None (1)'	System	25 Aug 2020 22:36:14

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:35:48', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bb408f61-a179-4715-9ff1-058cb2277402'	System	25 Aug 2020 22:36:14
User entered 'No (N)'	System	25 Aug 2020 22:36:14

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:35:56', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bb408f61-a179-4715-9ff1-058cb2277402'	System	25 Aug 2020 22:36:14
User entered 'No (N)'	System	25 Aug 2020 22:36:14

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:04', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bb408f61-a179-4715-9ff1-058cb2277402'	System	25 Aug 2020 22:36:14
User entered 'None (1)'	System	25 Aug 2020 22:36:14

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:08', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bb408f61-a179-4715-9ff1-058cb2277402'	System	25 Aug 2020 22:36:14
User entered '25 Aug 2020 17:36'	System	25 Aug 2020 22:36:14

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 17:01'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 19:31'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:17', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ba703744-7e49-4dea-9c6d-a51665dc0d5b'	System	26 Aug 2020 01:27:43
User entered 'None (1)'	System	26 Aug 2020 01:27:43

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:20', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ba703744-7e49-4dea-9c6d-a51665dc0d5b'	System	26 Aug 2020 01:27:43
User entered 'No (N)'	System	26 Aug 2020 01:27:43

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:27', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ba703744-7e49-4dea-9c6d-a51665dc0d5b'	System	26 Aug 2020 01:27:43
User entered 'No (N)'	System	26 Aug 2020 01:27:43

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:35', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ba703744-7e49-4dea-9c6d-a51665dc0d5b'	System	26 Aug 2020 01:27:43
User entered 'None (1)'	System	26 Aug 2020 01:27:43

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ba703744-7e49-4dea-9c6d-a51665dc0d5b'	System	26 Aug 2020 01:27:43
User entered '25 Aug 2020 20:27'	System	26 Aug 2020 01:27:43

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 20:26'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 2'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:04', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '651befc1-7f41-4803-a74e-3c67239ed970'	System	27 Aug 2020 00:24:37
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 00:24:37

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:07', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '651befc1-7f41-4803-a74e-3c67239ed970'	System	27 Aug 2020 00:24:37
User entered 'No (N)'	System	27 Aug 2020 00:24:37

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '651befc1-7f41-4803-a74e-3c67239ed970'	System	27 Aug 2020 00:24:37
User entered 'No (N)'	System	27 Aug 2020 00:24:37

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '651befc1-7f41-4803-a74e-3c67239ed970'	System	27 Aug 2020 00:24:37
User entered 'None (1)'	System	27 Aug 2020 00:24:37

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '651befc1-7f41-4803-a74e-3c67239ed970'	System	27 Aug 2020 00:24:37
User entered '26 Aug 2020 19:24'	System	27 Aug 2020 00:24:37

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 3'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:38', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ca01d48c-69ac-4d53-967b-5376eebc7325'	System	28 Aug 2020 01:08:05
User entered 'None (1)'	System	28 Aug 2020 01:08:05

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:41', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ca01d48c-69ac-4d53-967b-5376eebc7325'	System	28 Aug 2020 01:08:05
User entered 'No (N)'	System	28 Aug 2020 01:08:05

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:43', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ca01d48c-69ac-4d53-967b-5376eebc7325'	System	28 Aug 2020 01:08:05
User entered 'No (N)'	System	28 Aug 2020 01:08:05

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:55', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ca01d48c-69ac-4d53-967b-5376eebc7325'	System	28 Aug 2020 01:08:05
User entered 'None (1)'	System	28 Aug 2020 01:08:05

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:07:59', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ca01d48c-69ac-4d53-967b-5376eebc7325'	System	28 Aug 2020 01:08:05
User entered '27 Aug 2020 20:07'	System	28 Aug 2020 01:08:05

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 4'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:17:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '82d33705-5929-4ee4-8141-44fa800f1563'	System	29 Aug 2020 01:18:02
User entered 'None (1)'	System	29 Aug 2020 01:18:02

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:17:42', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '82d33705-5929-4ee4-8141-44fa800f1563'	System	29 Aug 2020 01:18:02
User entered 'No (N)'	System	29 Aug 2020 01:18:02

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:17:43', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '82d33705-5929-4ee4-8141-44fa800f1563'	System	29 Aug 2020 01:18:02
User entered 'No (N)'	System	29 Aug 2020 01:18:02

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:17:52', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '82d33705-5929-4ee4-8141-44fa800f1563'	System	29 Aug 2020 01:18:02
User entered 'None (1)'	System	29 Aug 2020 01:18:02

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:17:55', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '82d33705-5929-4ee4-8141-44fa800f1563'	System	29 Aug 2020 01:18:02
User entered '28 Aug 2020 20:17'	System	29 Aug 2020 01:18:02

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 5'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:06', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '54bd5138-7658-4cf0-9b5d-3b2578fa1d08'	System	30 Aug 2020 01:03:20
User entered 'None (1)'	System	30 Aug 2020 01:03:20

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:08', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '54bd5138-7658-4cf0-9b5d-3b2578fa1d08'	System	30 Aug 2020 01:03:20
User entered 'No (N)'	System	30 Aug 2020 01:03:20

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:11', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '54bd5138-7658-4cf0-9b5d-3b2578fa1d08'	System	30 Aug 2020 01:03:20
User entered 'No (N)'	System	30 Aug 2020 01:03:20

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:13', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '54bd5138-7658-4cf0-9b5d-3b2578fa1d08'	System	30 Aug 2020 01:03:20
User entered 'None (1)'	System	30 Aug 2020 01:03:20

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '54bd5138-7658-4cf0-9b5d-3b2578fa1d08'	System	30 Aug 2020 01:03:20
User entered '29 Aug 2020 20:03'	System	30 Aug 2020 01:03:20

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 6'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:17', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0bbb45b9-5e6e-4636-9efc-56ebdd50531c'	System	31 Aug 2020 03:47:35
User entered 'None (1)'	System	31 Aug 2020 03:47:35

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0bbb45b9-5e6e-4636-9efc-56ebdd50531c'	System	31 Aug 2020 03:47:35
User entered 'No (N)'	System	31 Aug 2020 03:47:35

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:23', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0bbb45b9-5e6e-4636-9efc-56ebdd50531c'	System	31 Aug 2020 03:47:35
User entered 'No (N)'	System	31 Aug 2020 03:47:35

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:25', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0bbb45b9-5e6e-4636-9efc-56ebdd50531c'	System	31 Aug 2020 03:47:35
User entered 'None (1)'	System	31 Aug 2020 03:47:35

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:47:28', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0bbb45b9-5e6e-4636-9efc-56ebdd50531c'	System	31 Aug 2020 03:47:35
User entered '30 Aug 2020 22:47'	System	31 Aug 2020 03:47:35

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 7'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:24', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'faa3dba3-6eb1-4bf8-bce4-394a50ed3ae6'	System	01 Sep 2020 01:03:41
User entered 'None (1)'	System	01 Sep 2020 01:03:41

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:26', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'faa3dba3-6eb1-4bf8-bce4-394a50ed3ae6'	System	01 Sep 2020 01:03:41
User entered 'No (N)'	System	01 Sep 2020 01:03:41

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:28', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'faa3dba3-6eb1-4bf8-bce4-394a50ed3ae6'	System	01 Sep 2020 01:03:41
User entered 'No (N)'	System	01 Sep 2020 01:03:41

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:30', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'faa3dba3-6eb1-4bf8-bce4-394a50ed3ae6'	System	01 Sep 2020 01:03:41
User entered 'None (1)'	System	01 Sep 2020 01:03:41

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'faa3dba3-6eb1-4bf8-bce4-394a50ed3ae6'	System	01 Sep 2020 01:03:41
User entered '31 Aug 2020 20:03'	System	01 Sep 2020 01:03:41

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '44d2fd81-fbd5-47ee-bab1-a105bb4bb489'	System	25 Aug 2020 22:36:49
User entered 'None (0)'	System	25 Aug 2020 22:36:49

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '44d2fd81-fbd5-47ee-bab1-a105bb4bb489'	System	25 Aug 2020 22:36:49
User entered 'None (0)'	System	25 Aug 2020 22:36:49

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:24', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '44d2fd81-fbd5-47ee-bab1-a105bb4bb489'	System	25 Aug 2020 22:36:49
User entered 'None (0)'	System	25 Aug 2020 22:36:49

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:31', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '44d2fd81-fbd5-47ee-bab1-a105bb4bb489'	System	25 Aug 2020 22:36:49
User entered 'None (0)'	System	25 Aug 2020 22:36:49

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:33', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '44d2fd81-fbd5-47ee-bab1-a105bb4bb489'	System	25 Aug 2020 22:36:49
User entered 'None (0)'	System	25 Aug 2020 22:36:49

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:35', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '44d2fd81-fbd5-47ee-bab1-a105bb4bb489'	System	25 Aug 2020 22:36:49
User entered 'None (0)'	System	25 Aug 2020 22:36:49

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:40', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '44d2fd81-fbd5-47ee-bab1-a105bb4bb489'	System	25 Aug 2020 22:36:49
User entered 'No (N)'	System	25 Aug 2020 22:36:49

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T17:36:44', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '44d2fd81-fbd5-47ee-bab1-a105bb4bb489'	System	25 Aug 2020 22:36:49
User entered '25 Aug 2020 17:36'	System	25 Aug 2020 22:36:49

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 17:01'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 19:31'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 1, after vaccination (at home)'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:45', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60076e11-091a-4ed8-88a7-884eee75d632'	System	26 Aug 2020 01:28:14
User entered 'None (0)'	System	26 Aug 2020 01:28:14

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:46', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60076e11-091a-4ed8-88a7-884eee75d632'	System	26 Aug 2020 01:28:14
User entered 'None (0)'	System	26 Aug 2020 01:28:14

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:48', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60076e11-091a-4ed8-88a7-884eee75d632'	System	26 Aug 2020 01:28:14
User entered 'None (0)'	System	26 Aug 2020 01:28:14

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:49', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60076e11-091a-4ed8-88a7-884eee75d632'	System	26 Aug 2020 01:28:14
User entered 'None (0)'	System	26 Aug 2020 01:28:14

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:52', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60076e11-091a-4ed8-88a7-884eee75d632'	System	26 Aug 2020 01:28:14
User entered 'None (0)'	System	26 Aug 2020 01:28:14

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:27:54', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60076e11-091a-4ed8-88a7-884eee75d632'	System	26 Aug 2020 01:28:14
User entered 'None (0)'	System	26 Aug 2020 01:28:14

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:28:07', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60076e11-091a-4ed8-88a7-884eee75d632'	System	26 Aug 2020 01:28:14
User entered 'No (N)'	System	26 Aug 2020 01:28:14

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-25T20:28:10', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60076e11-091a-4ed8-88a7-884eee75d632'	System	26 Aug 2020 01:28:14
User entered '25 Aug 2020 20:28'	System	26 Aug 2020 01:28:14

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Aug 2020 20:26'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 2'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '540599c4-2b0a-4bc9-bc32-1720eaff544f'	System	27 Aug 2020 00:25:12
User entered 'None (0)'	System	27 Aug 2020 00:25:12

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:25:04', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '540599c4-2b0a-4bc9-bc32-1720eaff544f'	System	27 Aug 2020 00:25:12
User entered 'None (0)'	System	27 Aug 2020 00:25:12

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:45', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '540599c4-2b0a-4bc9-bc32-1720eaff544f'	System	27 Aug 2020 00:25:12
User entered 'None (0)'	System	27 Aug 2020 00:25:12

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:52', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '540599c4-2b0a-4bc9-bc32-1720eaff544f'	System	27 Aug 2020 00:25:12
User entered 'None (0)'	System	27 Aug 2020 00:25:12

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:55', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '540599c4-2b0a-4bc9-bc32-1720eaff544f'	System	27 Aug 2020 00:25:12
User entered 'None (0)'	System	27 Aug 2020 00:25:12

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:56', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '540599c4-2b0a-4bc9-bc32-1720eaff544f'	System	27 Aug 2020 00:25:12
User entered 'None (0)'	System	27 Aug 2020 00:25:12

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:24:59', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '540599c4-2b0a-4bc9-bc32-1720eaff544f'	System	27 Aug 2020 00:25:12
User entered 'No (N)'	System	27 Aug 2020 00:25:12

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-26T19:25:08', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '540599c4-2b0a-4bc9-bc32-1720eaff544f'	System	27 Aug 2020 00:25:12
User entered '26 Aug 2020 19:25'	System	27 Aug 2020 00:25:12

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 3'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:08:04', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '917fcd16-aa44-4177-b14f-898500c1d60f'	System	28 Aug 2020 01:08:29
User entered 'None (0)'	System	28 Aug 2020 01:08:29

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:08:06', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '917fcd16-aa44-4177-b14f-898500c1d60f'	System	28 Aug 2020 01:08:29
User entered 'None (0)'	System	28 Aug 2020 01:08:29

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:08:07', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '917fcd16-aa44-4177-b14f-898500c1d60f'	System	28 Aug 2020 01:08:29
User entered 'None (0)'	System	28 Aug 2020 01:08:29

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:08:09', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '917fcd16-aa44-4177-b14f-898500c1d60f'	System	28 Aug 2020 01:08:29
User entered 'None (0)'	System	28 Aug 2020 01:08:29

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:08:10', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '917fcd16-aa44-4177-b14f-898500c1d60f'	System	28 Aug 2020 01:08:29
User entered 'None (0)'	System	28 Aug 2020 01:08:29

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:08:12', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '917fcd16-aa44-4177-b14f-898500c1d60f'	System	28 Aug 2020 01:08:29
User entered 'None (0)'	System	28 Aug 2020 01:08:29

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:08:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '917fcd16-aa44-4177-b14f-898500c1d60f'	System	28 Aug 2020 01:08:29
User entered 'No (N)'	System	28 Aug 2020 01:08:29

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-27T20:08:22', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '917fcd16-aa44-4177-b14f-898500c1d60f'	System	28 Aug 2020 01:08:29
User entered '27 Aug 2020 20:08'	System	28 Aug 2020 01:08:29

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 4'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:12', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a691221b-4e22-44d0-b500-65a151c4597e'	System	29 Aug 2020 01:18:30
User entered 'None (0)'	System	29 Aug 2020 01:18:30

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:13', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a691221b-4e22-44d0-b500-65a151c4597e'	System	29 Aug 2020 01:18:30
User entered 'None (0)'	System	29 Aug 2020 01:18:30

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:15', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a691221b-4e22-44d0-b500-65a151c4597e'	System	29 Aug 2020 01:18:30
User entered 'None (0)'	System	29 Aug 2020 01:18:30

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a691221b-4e22-44d0-b500-65a151c4597e'	System	29 Aug 2020 01:18:30
User entered 'None (0)'	System	29 Aug 2020 01:18:30

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a691221b-4e22-44d0-b500-65a151c4597e'	System	29 Aug 2020 01:18:30
User entered 'None (0)'	System	29 Aug 2020 01:18:30

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:19', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a691221b-4e22-44d0-b500-65a151c4597e'	System	29 Aug 2020 01:18:30
User entered 'None (0)'	System	29 Aug 2020 01:18:30

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:23', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a691221b-4e22-44d0-b500-65a151c4597e'	System	29 Aug 2020 01:18:30
User entered 'No (N)'	System	29 Aug 2020 01:18:30

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-28T20:18:26', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'a691221b-4e22-44d0-b500-65a151c4597e'	System	29 Aug 2020 01:18:30
User entered '28 Aug 2020 20:18'	System	29 Aug 2020 01:18:30

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 5'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:19', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '93e910ff-1ebd-481b-bd71-a381c429e4b4'	System	30 Aug 2020 01:03:36
User entered 'None (0)'	System	30 Aug 2020 01:03:36

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '93e910ff-1ebd-481b-bd71-a381c429e4b4'	System	30 Aug 2020 01:03:36
User entered 'None (0)'	System	30 Aug 2020 01:03:36

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:22', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '93e910ff-1ebd-481b-bd71-a381c429e4b4'	System	30 Aug 2020 01:03:36
User entered 'None (0)'	System	30 Aug 2020 01:03:36

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:24', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '93e910ff-1ebd-481b-bd71-a381c429e4b4'	System	30 Aug 2020 01:03:36
User entered 'None (0)'	System	30 Aug 2020 01:03:36

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:26', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '93e910ff-1ebd-481b-bd71-a381c429e4b4'	System	30 Aug 2020 01:03:36
User entered 'None (0)'	System	30 Aug 2020 01:03:36

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:28', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '93e910ff-1ebd-481b-bd71-a381c429e4b4'	System	30 Aug 2020 01:03:36
User entered 'None (0)'	System	30 Aug 2020 01:03:36

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:30', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '93e910ff-1ebd-481b-bd71-a381c429e4b4'	System	30 Aug 2020 01:03:36
User entered 'No (N)'	System	30 Aug 2020 01:03:36

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-29T20:03:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '93e910ff-1ebd-481b-bd71-a381c429e4b4'	System	30 Aug 2020 01:03:36
User entered '29 Aug 2020 20:03'	System	30 Aug 2020 01:03:36

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '30 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 6'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:44:56', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '175d517e-25f5-4a4b-8671-f22b08cde8f1'	System	31 Aug 2020 03:45:17
User entered 'None (0)'	System	31 Aug 2020 03:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:44:57', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '175d517e-25f5-4a4b-8671-f22b08cde8f1'	System	31 Aug 2020 03:45:17
User entered 'None (0)'	System	31 Aug 2020 03:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:44:59', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '175d517e-25f5-4a4b-8671-f22b08cde8f1'	System	31 Aug 2020 03:45:17
User entered 'None (0)'	System	31 Aug 2020 03:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:45:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '175d517e-25f5-4a4b-8671-f22b08cde8f1'	System	31 Aug 2020 03:45:17
User entered 'None (0)'	System	31 Aug 2020 03:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:45:02', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '175d517e-25f5-4a4b-8671-f22b08cde8f1'	System	31 Aug 2020 03:45:17
User entered 'None (0)'	System	31 Aug 2020 03:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:45:07', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '175d517e-25f5-4a4b-8671-f22b08cde8f1'	System	31 Aug 2020 03:45:17
User entered 'None (0)'	System	31 Aug 2020 03:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:45:08', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '175d517e-25f5-4a4b-8671-f22b08cde8f1'	System	31 Aug 2020 03:45:17
User entered 'No (N)'	System	31 Aug 2020 03:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-30T22:45:12', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '175d517e-25f5-4a4b-8671-f22b08cde8f1'	System	31 Aug 2020 03:45:17
User entered '30 Aug 2020 22:45'	System	31 Aug 2020 03:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '30 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '31 Aug 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 7'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:44', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '4c31c9cd-cd00-4990-8cfb-86f1c99f074a'	System	01 Sep 2020 01:04:04
User entered 'None (0)'	System	01 Sep 2020 01:04:04

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:45', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '4c31c9cd-cd00-4990-8cfb-86f1c99f074a'	System	01 Sep 2020 01:04:04
User entered 'None (0)'	System	01 Sep 2020 01:04:04

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:47', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '4c31c9cd-cd00-4990-8cfb-86f1c99f074a'	System	01 Sep 2020 01:04:04
User entered 'None (0)'	System	01 Sep 2020 01:04:04

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:50', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '4c31c9cd-cd00-4990-8cfb-86f1c99f074a'	System	01 Sep 2020 01:04:04
User entered 'None (0)'	System	01 Sep 2020 01:04:04

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:51', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '4c31c9cd-cd00-4990-8cfb-86f1c99f074a'	System	01 Sep 2020 01:04:04
User entered 'None (0)'	System	01 Sep 2020 01:04:04

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:53', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '4c31c9cd-cd00-4990-8cfb-86f1c99f074a'	System	01 Sep 2020 01:04:04
User entered 'None (0)'	System	01 Sep 2020 01:04:04

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:03:55', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '4c31c9cd-cd00-4990-8cfb-86f1c99f074a'	System	01 Sep 2020 01:04:04
User entered 'No (N)'	System	01 Sep 2020 01:04:04

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-08-31T20:04:01', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '4c31c9cd-cd00-4990-8cfb-86f1c99f074a'	System	01 Sep 2020 01:04:04
User entered '31 Aug 2020 20:04'	System	01 Sep 2020 01:04:04

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '31 Aug 2020 12:00'	System	25 Aug 2020 21:45:17

US3292316

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '01 Sep 2020 11:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:34
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 22:05:52

US3292316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:34
User entered '2 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 22:05:52

US3292316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:34
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 22:05:52

US3292316

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:34
User entered empty.	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 22:05:52

US3292316

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:40
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	02 Sep 2020 22:05:58

US3292316

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'l'	System	02 Sep 2020 22:05:58

US3292316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:59
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	09 Sep 2020 17:12:43

US3292316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:59
User entered '9 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	09 Sep 2020 17:12:43

US3292316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:59
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	09 Sep 2020 17:12:43

US3292316

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:04:59
User entered empty.	Kristy Trevino (b) (4) (b) (4)	09 Sep 2020 17:12:43

US3292316

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:05:24
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	09 Sep 2020 17:12:49

US3292316

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'l'	System	09 Sep 2020 17:12:49

US3292316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:06:52
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 22:28:44

US3292316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:06:52
User entered '15 Sep 2020'	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 22:28:44

US3292316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:06:52
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 22:28:44

US3292316

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:06:52
User entered empty.	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 22:28:44

US3292316

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:06:56
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	15 Sep 2020 22:28:57

US3292316

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'l'	System	15 Sep 2020 22:28:57

US3292316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:21:50
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:36:33

US3292316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:21:50
User entered '22 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:36:33

US3292316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:21:50
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:36:33

US3292316

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'VISIT2'	System	22 Sep 2020 20:36:33

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User accepted default value 'Pre-Dose (PREDOSE)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '22 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '14:16'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '22 Sep 2020 14:16'	System	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '36.8' C	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered 'Oral (Oral)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered empty.	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '85'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'bpm'	System	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '16'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'breaths/min'	System	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '126'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'mmHg'	System	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '83'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'mmHg'	System	22 Sep 2020 20:39:03

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User accepted default value 'Post-Dose (POSTDOSE)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '22 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '15:23'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '22 Sep 2020 15:23'	System	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '36.7' C	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered 'Oral (Oral)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered empty.	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '84'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'bpm'	System	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '16'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'breaths/min'	System	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '124'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'mmHg'	System	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:22
User entered '83'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'mmHg'	System	22 Sep 2020 20:39:35

US3292316

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:35
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:51

US3292316

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:23:35
User entered '22 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:39:51

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:44
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:44
User entered empty.	Nathan Cortez (b) (4)	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:44
User entered empty.	Nathan Cortez (b) (4)	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'MRNA-1273 OR PLACEBO'	System	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[What was the treatment date? \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:44
User entered '22 Sep 2020'	Nathan Cortez (b) (4)	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:44
User entered '14:52'	Nathan Cortez (b) (4)	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '22 Sep 2020 14:52'	System	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

Which arm was used to give treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:44
User closed query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	22 Sep 2020 19:55:44
Query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' answered by data change (Site from System).	System	22 Sep 2020 19:55:44
User entered 'Right Arm (RIGHT ARM)' reason for change: Data Entry Error	Nathan Cortez (b) (4)	22 Sep 2020 19:55:44
User opened query 'Treatment Arm does not match first dose. Per protocol, the second dose should be administered in the same arm as the first dose.' (Site from System).	System	22 Sep 2020 19:55:39
User entered 'Left Arm (LEFT ARM)'	Nathan Cortez (b) (4)	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
DataPoint Verified.		29 Jan 2021 17:24:44
User entered 'ONCE'	System	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 16:31:58

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'INTRAMUSCULAR'	System	22 Sep 2020 19:55:39

US3292316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:58
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:09

US3292316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:58
User entered '22 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:09

US3292316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:24:58
User entered '14:28'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:09

US3292316

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '22 Sep 2020 14:28'	System	22 Sep 2020 20:40:09

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 16:31:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:25:09
User entered '22 Sep 2020'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:31:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:25:09
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:31:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:25:09
User entered '14:35'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 16:31:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '22 Sep 2020 14:35'	System	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:31:58

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:25:09
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:31:58

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:25:09
User entered empty.	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 16:31:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered empty.	System	22 Sep 2020 20:40:24

US3292316

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:25:16
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	22 Sep 2020 20:40:30

US3292316

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'I'	System	22 Sep 2020 20:40:30

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:24:54', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'f00569a2-4f26-4222-a00b-c1e6e048d40c'	System	22 Sep 2020 20:25:10
User entered 'Yes (Y)'	System	22 Sep 2020 20:25:10

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:24:58', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'f00569a2-4f26-4222-a00b-c1e6e048d40c'	System	22 Sep 2020 20:25:10
User entered '98.0'	System	22 Sep 2020 20:25:10

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:01', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'f00569a2-4f26-4222-a00b-c1e6e048d40c'	System	22 Sep 2020 20:25:10
User entered 'No (N)'	System	22 Sep 2020 20:25:10

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:04', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'f00569a2-4f26-4222-a00b-c1e6e048d40c'	System	22 Sep 2020 20:25:10
User entered '22 Sep 2020 15:25'	System	22 Sep 2020 20:25:10

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 15:12'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 17:42'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:52:53', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'cee58093-1537-49d0-b7d5-995577d4b1d2'	System	23 Sep 2020 06:53:07
User entered 'Yes (Y)'	System	23 Sep 2020 06:53:07

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:52:58', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'cee58093-1537-49d0-b7d5-995577d4b1d2' User entered '96.7'	System	23 Sep 2020 06:53:07
	System	23 Sep 2020 06:53:07

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'cee58093-1537-49d0-b7d5-995577d4b1d2'	System	23 Sep 2020 06:53:07
User entered 'No (N)'	System	23 Sep 2020 06:53:07

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:03', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'cee58093-1537-49d0-b7d5-995577d4b1d2'	System	23 Sep 2020 06:53:07
User entered '23 Sep 2020 01:53'	System	23 Sep 2020 06:53:07

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 18:37'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 2'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:56:29', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0f766910-82d1-4d1b-b415-5c2f3fe86c37'	System	23 Sep 2020 23:56:43
User entered 'Yes (Y)'	System	23 Sep 2020 23:56:43

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:56:33', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0f766910-82d1-4d1b-b415-5c2f3fe86c37'	System	23 Sep 2020 23:56:43
User entered '99.1'	System	23 Sep 2020 23:56:43

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:56:35', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0f766910-82d1-4d1b-b415-5c2f3fe86c37'	System	23 Sep 2020 23:56:43
User entered 'No (N)'	System	23 Sep 2020 23:56:43

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:56:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '0f766910-82d1-4d1b-b415-5c2f3fe86c37'	System	23 Sep 2020 23:56:43
User entered '23 Sep 2020 18:56'	System	23 Sep 2020 23:56:43

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 3'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-24T23:59:45', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '886ba898-2f5d-46b3-875f-b5a8f26f0e89'	System	25 Sep 2020 05:00:42
User entered 'Yes (Y)'	System	25 Sep 2020 05:00:42

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-24T23:59:54', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '886ba898-2f5d-46b3-875f-b5a8f26f0e89'	System	25 Sep 2020 05:00:42
User entered '98.2'	System	25 Sep 2020 05:00:42

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-24T23:59:56', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '886ba898-2f5d-46b3-875f-b5a8f26f0e89'	System	25 Sep 2020 05:00:42
User entered 'No (N)'	System	25 Sep 2020 05:00:42

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-24T23:59:58', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '886ba898-2f5d-46b3-875f-b5a8f26f0e89'	System	25 Sep 2020 05:00:42
User entered '24 Sep 2020 23:59'	System	25 Sep 2020 05:00:42

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 4'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:02:42', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd62ef237-8eaa-4827-b52b-4c9c7e1b2c97'	System	26 Sep 2020 01:11:15
User entered 'Yes (Y)'	System	26 Sep 2020 01:11:15

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:02:47', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd62ef237-8eaa-4827-b52b-4c9c7e1b2c97'	System	26 Sep 2020 01:11:15
User entered '97.5'	System	26 Sep 2020 01:11:15

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:02:54', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd62ef237-8eaa-4827-b52b-4c9c7e1b2c97'	System	26 Sep 2020 01:11:15
User entered 'No (N)'	System	26 Sep 2020 01:11:15

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:02:56', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd62ef237-8eaa-4827-b52b-4c9c7e1b2c97'	System	26 Sep 2020 01:11:15
User entered '25 Sep 2020 20:02'	System	26 Sep 2020 01:11:15

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 5'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:14', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'dd950ae9-a8e9-41d5-9f2d-a2798eb5a1a4'	System	27 Sep 2020 03:09:32
User entered 'Yes (Y)'	System	27 Sep 2020 03:09:32

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'dd950ae9-a8e9-41d5-9f2d-a2798eb5a1a4'	System	27 Sep 2020 03:09:32
User entered '97.9'	System	27 Sep 2020 03:09:32

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:23', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'dd950ae9-a8e9-41d5-9f2d-a2798eb5a1a4'	System	27 Sep 2020 03:09:32
User entered 'No (N)'	System	27 Sep 2020 03:09:32

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:28', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'dd950ae9-a8e9-41d5-9f2d-a2798eb5a1a4'	System	27 Sep 2020 03:09:32
User entered '26 Sep 2020 22:09'	System	27 Sep 2020 03:09:32

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 6'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:29', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '05fa97fc-92bf-4431-868e-bc5ebaff81db'	System	28 Sep 2020 11:45:41
User entered 'Yes (Y)'	System	28 Sep 2020 11:45:41

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:34', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '05fa97fc-92bf-4431-868e-bc5ebaff81db'	System	28 Sep 2020 11:45:41
User entered '94.3'	System	28 Sep 2020 11:45:41

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:36', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '05fa97fc-92bf-4431-868e-bc5ebaff81db'	System	28 Sep 2020 11:45:41
User entered 'No (N)'	System	28 Sep 2020 11:45:41

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '05fa97fc-92bf-4431-868e-bc5ebaff81db'	System	28 Sep 2020 11:45:41
User entered '28 Sep 2020 06:45'	System	28 Sep 2020 11:45:41

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 7'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:02:58', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd3ae07af-9d41-43a0-8cca-e26c241b61ab'	System	29 Sep 2020 01:03:11
User entered 'Yes (Y)'	System	29 Sep 2020 01:03:11

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:01', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd3ae07af-9d41-43a0-8cca-e26c241b61ab'	System	29 Sep 2020 01:03:11
User entered '97.7'	System	29 Sep 2020 01:03:11

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:03', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd3ae07af-9d41-43a0-8cca-e26c241b61ab'	System	29 Sep 2020 01:03:11
User entered 'No (N)'	System	29 Sep 2020 01:03:11

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:08', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd3ae07af-9d41-43a0-8cca-e26c241b61ab'	System	29 Sep 2020 01:03:11
User entered '28 Sep 2020 20:03'	System	29 Sep 2020 01:03:11

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:07', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ea985860-5b3d-4fc0-8b83-85a82c1e17a8'	System	22 Sep 2020 20:25:26
User entered 'None (1)'	System	22 Sep 2020 20:25:26

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:12', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ea985860-5b3d-4fc0-8b83-85a82c1e17a8'	System	22 Sep 2020 20:25:26
User entered 'No (N)'	System	22 Sep 2020 20:25:26

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:14', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ea985860-5b3d-4fc0-8b83-85a82c1e17a8'	System	22 Sep 2020 20:25:26
User entered 'No (N)'	System	22 Sep 2020 20:25:26

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ea985860-5b3d-4fc0-8b83-85a82c1e17a8'	System	22 Sep 2020 20:25:26
User entered 'None (1)'	System	22 Sep 2020 20:25:26

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:22', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ea985860-5b3d-4fc0-8b83-85a82c1e17a8'	System	22 Sep 2020 20:25:26
User entered '22 Sep 2020 15:25'	System	22 Sep 2020 20:25:26

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 15:12'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 17:42'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:06', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e288e5d7-9c6e-488a-b821-a77383d5cfd3'	System	23 Sep 2020 06:53:19
User entered 'None (1)'	System	23 Sep 2020 06:53:19

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:09', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e288e5d7-9c6e-488a-b821-a77383d5cfd3'	System	23 Sep 2020 06:53:19
User entered 'No (N)'	System	23 Sep 2020 06:53:19

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:10', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e288e5d7-9c6e-488a-b821-a77383d5cfd3'	System	23 Sep 2020 06:53:19
User entered 'No (N)'	System	23 Sep 2020 06:53:19

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:12', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e288e5d7-9c6e-488a-b821-a77383d5cfd3'	System	23 Sep 2020 06:53:19
User entered 'None (1)'	System	23 Sep 2020 06:53:19

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e288e5d7-9c6e-488a-b821-a77383d5cfd3'	System	23 Sep 2020 06:53:19
User entered '23 Sep 2020 01:53'	System	23 Sep 2020 06:53:19

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 18:37'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 2'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:57:13', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '36bac74f-9ca5-44ad-94a9-0690e1fda901'	System	23 Sep 2020 23:57:53
User entered 'Does not interfere with activity (2)'	System	23 Sep 2020 23:57:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:57:17', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '36bac74f-9ca5-44ad-94a9-0690e1fda901'	System	23 Sep 2020 23:57:53
User entered 'No (N)'	System	23 Sep 2020 23:57:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:57:19', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '36bac74f-9ca5-44ad-94a9-0690e1fda901'	System	23 Sep 2020 23:57:53
User entered 'Yes (Y)'	System	23 Sep 2020 23:57:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:57:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '36bac74f-9ca5-44ad-94a9-0690e1fda901'	System	23 Sep 2020 23:57:53
User entered '7'	System	23 Sep 2020 23:57:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:57:46', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '36bac74f-9ca5-44ad-94a9-0690e1fda901'	System	23 Sep 2020 23:57:53
User entered 'None (1)'	System	23 Sep 2020 23:57:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:57:50', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '36bac74f-9ca5-44ad-94a9-0690e1fda901'	System	23 Sep 2020 23:57:53
User entered '23 Sep 2020 18:57'	System	23 Sep 2020 23:57:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 3'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:03', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '8487aa24-7be8-4b7c-a393-6a1d54c22927'	System	25 Sep 2020 05:01:37
User entered 'None (1)'	System	25 Sep 2020 05:01:37

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:06', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '8487aa24-7be8-4b7c-a393-6a1d54c22927'	System	25 Sep 2020 05:01:37
User entered 'No (N)'	System	25 Sep 2020 05:01:37

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '8487aa24-7be8-4b7c-a393-6a1d54c22927'	System	25 Sep 2020 05:01:37
User entered 'Yes (Y)'	System	25 Sep 2020 05:01:37

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '8487aa24-7be8-4b7c-a393-6a1d54c22927'	System	25 Sep 2020 05:01:37
User entered '2'	System	25 Sep 2020 05:01:37

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '8487aa24-7be8-4b7c-a393-6a1d54c22927'	System	25 Sep 2020 05:01:37
User entered 'None (1)'	System	25 Sep 2020 05:01:37

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:23', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '8487aa24-7be8-4b7c-a393-6a1d54c22927'	System	25 Sep 2020 05:01:37
User entered '25 Sep 2020 00:00'	System	25 Sep 2020 05:01:37

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 4'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:03:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '645a35ba-21a1-426f-b59a-2cc994c092c2'	System	26 Sep 2020 01:11:55
User entered 'None (1)'	System	26 Sep 2020 01:11:55

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:03:03', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '645a35ba-21a1-426f-b59a-2cc994c092c2'	System	26 Sep 2020 01:11:55
User entered 'No (N)'	System	26 Sep 2020 01:11:55

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:03:20', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '645a35ba-21a1-426f-b59a-2cc994c092c2'	System	26 Sep 2020 01:11:55
User entered 'Yes (Y)'	System	26 Sep 2020 01:11:55

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:03:42', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '645a35ba-21a1-426f-b59a-2cc994c092c2'	System	26 Sep 2020 01:11:55
User entered '2'	System	26 Sep 2020 01:11:55

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:03:57', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '645a35ba-21a1-426f-b59a-2cc994c092c2'	System	26 Sep 2020 01:11:55
User entered 'None (1)'	System	26 Sep 2020 01:11:55

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:01', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '645a35ba-21a1-426f-b59a-2cc994c092c2'	System	26 Sep 2020 01:11:55
User entered '25 Sep 2020 20:04'	System	26 Sep 2020 01:11:55

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 5'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:31', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bc2927c6-67d1-48a4-923f-338c7af516c9'	System	27 Sep 2020 03:09:44
User entered 'None (1)'	System	27 Sep 2020 03:09:44

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:33', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bc2927c6-67d1-48a4-923f-338c7af516c9'	System	27 Sep 2020 03:09:44
User entered 'No (N)'	System	27 Sep 2020 03:09:44

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:35', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bc2927c6-67d1-48a4-923f-338c7af516c9'	System	27 Sep 2020 03:09:44
User entered 'No (N)'	System	27 Sep 2020 03:09:44

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:37', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bc2927c6-67d1-48a4-923f-338c7af516c9'	System	27 Sep 2020 03:09:44
User entered 'None (1)'	System	27 Sep 2020 03:09:44

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:40', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bc2927c6-67d1-48a4-923f-338c7af516c9'	System	27 Sep 2020 03:09:44
User entered '26 Sep 2020 22:09'	System	27 Sep 2020 03:09:44

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 6'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:42', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5c5a0cdf-d1bc-440a-b8d0-bf69c234822d'	System	28 Sep 2020 11:45:53
User entered 'None (1)'	System	28 Sep 2020 11:45:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:44', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5c5a0cdf-d1bc-440a-b8d0-bf69c234822d'	System	28 Sep 2020 11:45:53
User entered 'No (N)'	System	28 Sep 2020 11:45:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:45', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5c5a0cdf-d1bc-440a-b8d0-bf69c234822d'	System	28 Sep 2020 11:45:53
User entered 'No (N)'	System	28 Sep 2020 11:45:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:47', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5c5a0cdf-d1bc-440a-b8d0-bf69c234822d'	System	28 Sep 2020 11:45:53
User entered 'None (1)'	System	28 Sep 2020 11:45:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:49', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5c5a0cdf-d1bc-440a-b8d0-bf69c234822d'	System	28 Sep 2020 11:45:53
User entered '28 Sep 2020 06:45'	System	28 Sep 2020 11:45:53

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 7'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:11', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '406e5d3c-ec9f-40c0-b0ba-57ff614f607e'	System	29 Sep 2020 01:03:23
User entered 'None (1)'	System	29 Sep 2020 01:03:23

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:13', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '406e5d3c-ec9f-40c0-b0ba-57ff614f607e'	System	29 Sep 2020 01:03:23
User entered 'No (N)'	System	29 Sep 2020 01:03:23

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:14', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '406e5d3c-ec9f-40c0-b0ba-57ff614f607e'	System	29 Sep 2020 01:03:23
User entered 'No (N)'	System	29 Sep 2020 01:03:23

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '406e5d3c-ec9f-40c0-b0ba-57ff614f607e'	System	29 Sep 2020 01:03:23
User entered 'None (1)'	System	29 Sep 2020 01:03:23

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '406e5d3c-ec9f-40c0-b0ba-57ff614f607e'	System	29 Sep 2020 01:03:23
User entered '28 Sep 2020 20:03'	System	29 Sep 2020 01:03:23

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:25', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df773e1a-eae5-4288-ace1-0681d9ed7981'	System	22 Sep 2020 20:25:47
User entered 'None (0)'	System	22 Sep 2020 20:25:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:27', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df773e1a-eae5-4288-ace1-0681d9ed7981'	System	22 Sep 2020 20:25:47
User entered 'None (0)'	System	22 Sep 2020 20:25:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:29', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df773e1a-eae5-4288-ace1-0681d9ed7981'	System	22 Sep 2020 20:25:47
User entered 'None (0)'	System	22 Sep 2020 20:25:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:30', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df773e1a-eae5-4288-ace1-0681d9ed7981'	System	22 Sep 2020 20:25:47
User entered 'None (0)'	System	22 Sep 2020 20:25:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df773e1a-eae5-4288-ace1-0681d9ed7981'	System	22 Sep 2020 20:25:47
User entered 'None (0)'	System	22 Sep 2020 20:25:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:34', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df773e1a-eae5-4288-ace1-0681d9ed7981'	System	22 Sep 2020 20:25:47
User entered 'None (0)'	System	22 Sep 2020 20:25:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:40', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df773e1a-eae5-4288-ace1-0681d9ed7981'	System	22 Sep 2020 20:25:47
User entered 'No (N)'	System	22 Sep 2020 20:25:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-22T15:25:43', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df773e1a-eae5-4288-ace1-0681d9ed7981'	System	22 Sep 2020 20:25:47
User entered '22 Sep 2020 15:25'	System	22 Sep 2020 20:25:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 15:12'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 17:42'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 1, after vaccination (at home)'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e6a96d96-1269-47fe-97fb-cd4f83f8ec7f'	System	23 Sep 2020 06:53:35
User entered 'None (0)'	System	23 Sep 2020 06:53:35

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:20', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e6a96d96-1269-47fe-97fb-cd4f83f8ec7f'	System	23 Sep 2020 06:53:35
User entered 'None (0)'	System	23 Sep 2020 06:53:35

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e6a96d96-1269-47fe-97fb-cd4f83f8ec7f'	System	23 Sep 2020 06:53:35
User entered 'None (0)'	System	23 Sep 2020 06:53:35

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:22', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e6a96d96-1269-47fe-97fb-cd4f83f8ec7f' User entered 'None (0)'	System	23 Sep 2020 06:53:35
	System	23 Sep 2020 06:53:35

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:24', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e6a96d96-1269-47fe-97fb-cd4f83f8ec7f'	System	23 Sep 2020 06:53:35
User entered 'None (0)'	System	23 Sep 2020 06:53:35

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:25', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e6a96d96-1269-47fe-97fb-cd4f83f8ec7f'	System	23 Sep 2020 06:53:35
User entered 'None (0)'	System	23 Sep 2020 06:53:35

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:28', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e6a96d96-1269-47fe-97fb-cd4f83f8ec7f'	System	23 Sep 2020 06:53:35
User entered 'No (N)'	System	23 Sep 2020 06:53:35

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T01:53:31', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e6a96d96-1269-47fe-97fb-cd4f83f8ec7f'	System	23 Sep 2020 06:53:35
User entered '23 Sep 2020 01:53'	System	23 Sep 2020 06:53:35

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '22 Sep 2020 18:37'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '23 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 2'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:57:54', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df927ce0-fd3f-4622-9d47-e615fa1586df' User entered 'None (0)'	System	23 Sep 2020 23:58:41
	System	23 Sep 2020 23:58:41

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:58:06', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df927ce0-fd3f-4622-9d47-e615fa1586df'	System	23 Sep 2020 23:58:41
User entered 'None (0)'	System	23 Sep 2020 23:58:41

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:58:10', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df927ce0-fd3f-4622-9d47-e615fa1586df'	System	23 Sep 2020 23:58:41
User entered 'None (0)'	System	23 Sep 2020 23:58:41

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:58:13', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df927ce0-fd3f-4622-9d47-e615fa1586df'	System	23 Sep 2020 23:58:41
User entered 'None (0)'	System	23 Sep 2020 23:58:41

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:58:23', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df927ce0-fd3f-4622-9d47-e615fa1586df'	System	23 Sep 2020 23:58:41
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	23 Sep 2020 23:58:41

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:58:26', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df927ce0-fd3f-4622-9d47-e615fa1586df'	System	23 Sep 2020 23:58:41
User entered 'None (0)'	System	23 Sep 2020 23:58:41

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:58:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df927ce0-fd3f-4622-9d47-e615fa1586df'	System	23 Sep 2020 23:58:41
User entered 'No (N)'	System	23 Sep 2020 23:58:41

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-23T18:58:38', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'df927ce0-fd3f-4622-9d47-e615fa1586df'	System	23 Sep 2020 23:58:41
User entered '23 Sep 2020 18:58'	System	23 Sep 2020 23:58:41

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '23 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '24 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 3'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:26', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '68738db1-e2ea-474c-a800-4f8ab4a9f58c'	System	25 Sep 2020 05:01:45
User entered 'None (0)'	System	25 Sep 2020 05:01:45

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:27', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '68738db1-e2ea-474c-a800-4f8ab4a9f58c'	System	25 Sep 2020 05:01:45
User entered 'None (0)'	System	25 Sep 2020 05:01:45

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:29', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '68738db1-e2ea-474c-a800-4f8ab4a9f58c'	System	25 Sep 2020 05:01:45
User entered 'None (0)'	System	25 Sep 2020 05:01:45

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:30', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '68738db1-e2ea-474c-a800-4f8ab4a9f58c'	System	25 Sep 2020 05:01:45
User entered 'None (0)'	System	25 Sep 2020 05:01:45

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '68738db1-e2ea-474c-a800-4f8ab4a9f58c'	System	25 Sep 2020 05:01:45
User entered 'None (0)'	System	25 Sep 2020 05:01:45

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:34', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '68738db1-e2ea-474c-a800-4f8ab4a9f58c'	System	25 Sep 2020 05:01:45
User entered 'None (0)'	System	25 Sep 2020 05:01:45

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:37', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '68738db1-e2ea-474c-a800-4f8ab4a9f58c'	System	25 Sep 2020 05:01:45
User entered 'No (N)'	System	25 Sep 2020 05:01:45

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T00:00:40', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '68738db1-e2ea-474c-a800-4f8ab4a9f58c'	System	25 Sep 2020 05:01:45
User entered '25 Sep 2020 00:00'	System	25 Sep 2020 05:01:45

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '24 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 4'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:08', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60d42dfe-34f1-4a5a-bdcb-4d7ea1b6c906'	System	26 Sep 2020 01:14:31
User entered 'None (0)'	System	26 Sep 2020 01:14:31

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:10', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60d42dfe-34f1-4a5a-bdcb-4d7ea1b6c906'	System	26 Sep 2020 01:14:31
User entered 'None (0)'	System	26 Sep 2020 01:14:31

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:12', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60d42dfe-34f1-4a5a-bdcb-4d7ea1b6c906'	System	26 Sep 2020 01:14:31
User entered 'None (0)'	System	26 Sep 2020 01:14:31

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:14', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60d42dfe-34f1-4a5a-bdcb-4d7ea1b6c906'	System	26 Sep 2020 01:14:31
User entered 'None (0)'	System	26 Sep 2020 01:14:31

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60d42dfe-34f1-4a5a-bdcb-4d7ea1b6c906'	System	26 Sep 2020 01:14:31
User entered 'None (0)'	System	26 Sep 2020 01:14:31

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:23', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60d42dfe-34f1-4a5a-bdcb-4d7ea1b6c906'	System	26 Sep 2020 01:14:31
User entered 'None (0)'	System	26 Sep 2020 01:14:31

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:27', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60d42dfe-34f1-4a5a-bdcb-4d7ea1b6c906'	System	26 Sep 2020 01:14:31
User entered 'No (N)'	System	26 Sep 2020 01:14:31

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-25T20:04:31', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '60d42dfe-34f1-4a5a-bdcB-4d7ea1b6c906'	System	26 Sep 2020 01:14:31
User entered '25 Sep 2020 20:04'	System	26 Sep 2020 01:14:31

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '25 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 5'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:44', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c51ec82-f7b9-49a8-83b6-9824b8fe9136'	System	27 Sep 2020 03:10:08
User entered 'None (0)'	System	27 Sep 2020 03:10:08

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:45', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c51ec82-f7b9-49a8-83b6-9824b8fe9136'	System	27 Sep 2020 03:10:08
User entered 'None (0)'	System	27 Sep 2020 03:10:08

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:46', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c51ec82-f7b9-49a8-83b6-9824b8fe9136'	System	27 Sep 2020 03:10:08
User entered 'None (0)'	System	27 Sep 2020 03:10:08

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:48', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c51ec82-f7b9-49a8-83b6-9824b8fe9136'	System	27 Sep 2020 03:10:08
User entered 'None (0)'	System	27 Sep 2020 03:10:08

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:49', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c51ec82-f7b9-49a8-83b6-9824b8fe9136'	System	27 Sep 2020 03:10:08
User entered 'None (0)'	System	27 Sep 2020 03:10:08

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:50', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c51ec82-f7b9-49a8-83b6-9824b8fe9136'	System	27 Sep 2020 03:10:08
User entered 'None (0)'	System	27 Sep 2020 03:10:08

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:09:59', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c51ec82-f7b9-49a8-83b6-9824b8fe9136'	System	27 Sep 2020 03:10:08
User entered 'No (N)'	System	27 Sep 2020 03:10:08

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-26T22:10:02', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c51ec82-f7b9-49a8-83b6-9824b8fe9136'	System	27 Sep 2020 03:10:08
User entered '26 Sep 2020 22:10'	System	27 Sep 2020 03:10:08

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '26 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 6'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:55', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '7b8a4558-66f0-4cad-a128-cd791e614003'	System	28 Sep 2020 11:46:12
User entered 'None (0)'	System	28 Sep 2020 11:46:12

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:56', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '7b8a4558-66f0-4cad-a128-cd791e614003'	System	28 Sep 2020 11:46:12
User entered 'None (0)'	System	28 Sep 2020 11:46:12

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:58', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '7b8a4558-66f0-4cad-a128-cd791e614003'	System	28 Sep 2020 11:46:12
User entered 'None (0)'	System	28 Sep 2020 11:46:12

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:45:59', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '7b8a4558-66f0-4cad-a128-cd791e614003'	System	28 Sep 2020 11:46:12
User entered 'None (0)'	System	28 Sep 2020 11:46:12

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:46:01', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '7b8a4558-66f0-4cad-a128-cd791e614003'	System	28 Sep 2020 11:46:12
User entered 'None (0)'	System	28 Sep 2020 11:46:12

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:46:02', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '7b8a4558-66f0-4cad-a128-cd791e614003'	System	28 Sep 2020 11:46:12
User entered 'None (0)'	System	28 Sep 2020 11:46:12

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:46:05', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '7b8a4558-66f0-4cad-a128-cd791e614003'	System	28 Sep 2020 11:46:12
User entered 'No (N)'	System	28 Sep 2020 11:46:12

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T06:46:09', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '7b8a4558-66f0-4cad-a128-cd791e614003'	System	28 Sep 2020 11:46:12
User entered '28 Sep 2020 06:46'	System	28 Sep 2020 11:46:12

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '27 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	22 Sep 2020 19:55:39
User entered 'Day 7'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:21', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c3ec122-79c3-4523-85ff-c0b72e63b6ba'	System	29 Sep 2020 01:03:47
User entered 'None (0)'	System	29 Sep 2020 01:03:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:22', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c3ec122-79c3-4523-85ff-c0b72e63b6ba'	System	29 Sep 2020 01:03:47
User entered 'None (0)'	System	29 Sep 2020 01:03:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:24', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c3ec122-79c3-4523-85ff-c0b72e63b6ba'	System	29 Sep 2020 01:03:47
User entered 'None (0)'	System	29 Sep 2020 01:03:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:25', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c3ec122-79c3-4523-85ff-c0b72e63b6ba'	System	29 Sep 2020 01:03:47
User entered 'None (0)'	System	29 Sep 2020 01:03:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:26', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c3ec122-79c3-4523-85ff-c0b72e63b6ba'	System	29 Sep 2020 01:03:47
User entered 'None (0)'	System	29 Sep 2020 01:03:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:27', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c3ec122-79c3-4523-85ff-c0b72e63b6ba'	System	29 Sep 2020 01:03:47
User entered 'None (0)'	System	29 Sep 2020 01:03:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:29', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c3ec122-79c3-4523-85ff-c0b72e63b6ba'	System	29 Sep 2020 01:03:47
User entered 'No (N)'	System	29 Sep 2020 01:03:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-09-28T20:03:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c3ec122-79c3-4523-85ff-c0b72e63b6ba'	System	29 Sep 2020 01:03:47
User entered '28 Sep 2020 20:03'	System	29 Sep 2020 01:03:47

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '28 Sep 2020 12:00'	System	22 Sep 2020 19:55:39

US3292316

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 16:31:58

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
User entered '29 Sep 2020 11:59'	System	22 Sep 2020 19:55:39

US3292316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:09
User entered 'Yes (Y)'		29 Sep 2020 17:34:04

US3292316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:09
User entered '29 Sep 2020'		29 Sep 2020 17:34:04

US3292316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:09
User entered 'Contact Made (CONTACT MADE)'		29 Sep 2020 17:34:04

US3292316

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:09
User entered empty.		29 Sep 2020 17:34:04

US3292316

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:15
User entered 'Yes (Y)'		29 Sep 2020 17:34:13

US3292316

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'I'	System	29 Sep 2020 17:34:13

US3292316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:57
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	06 Oct 2020 20:13:20

US3292316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:57
User entered '6 Oct 2020'	Kristy Trevino (b) (4) (b) (4)	06 Oct 2020 20:13:20

US3292316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:57
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	06 Oct 2020 20:13:20

US3292316

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:07:57
User entered empty.	Kristy Trevino (b) (4) (b) (4)	06 Oct 2020 20:13:20

US3292316

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:08:00
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	06 Oct 2020 20:13:39

US3292316

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'l'	System	06 Oct 2020 20:13:39

US3292316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:08:20
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	13 Oct 2020 18:46:55

US3292316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:08:20
User entered '13 Oct 2020'	Kristy Trevino (b) (4) (b) (4)	13 Oct 2020 18:46:55

US3292316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:08:20
User entered 'Contact Made (CONTACT MADE)'	Kristy Trevino (b) (4) (b) (4)	13 Oct 2020 18:46:55

US3292316

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:08:20
User entered empty.	Kristy Trevino (b) (4) (b) (4)	13 Oct 2020 18:46:55

US3292316

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:08:23
User entered 'Yes (Y)'	Kristy Trevino (b) (4) (b) (4)	13 Oct 2020 18:47:01

US3292316

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'l'	System	13 Oct 2020 18:47:01

US3292316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:09:48
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:33:52

US3292316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:09:48
User entered '21 Oct 2020'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:33:52

US3292316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:09:48
User entered 'Clinic (Clinic)'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:33:52

US3292316

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User entered 'VISIT3'	System	21 Oct 2020 20:33:52

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered '21 Oct 2020'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered '09:30'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User entered '21 Oct 2020 09:30'	System	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered '36.6' C	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered 'Oral (Oral)'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered empty.	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered '84'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User entered 'bpm'	System	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered '20'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User entered 'breaths/min'	System	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered '124'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User entered 'mmHg'	System	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:11
User entered '87'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User entered 'mmHg'	System	21 Oct 2020 20:35:21

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53

US3292316

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53

US3292316

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:53
User entered 'No (N)'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:26

US3292316

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:53
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:11:53
User entered empty.	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:26

US3292316

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:12:06
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:48

US3292316

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:12:06
User entered '21 Oct 2020'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:48

US3292316

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:12:06
User entered '10:06'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:48

US3292316

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered '21 Oct 2020 10:06'	System	21 Oct 2020 20:35:48

US3292316

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:12:14
User entered 'Yes (Y)'	Kevin Martinez (b) (4) (b) (4)	21 Oct 2020 20:35:53

US3292316

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'I'	System	21 Oct 2020 20:35:53

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 64'	System	25 Aug 2020 21:45:17

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-10-27T15:32:15', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd69f9f16-86b2-4ef1-aa40-3a556b3fd2ea'	System	27 Oct 2020 20:32:48
User entered 'No (N)'	System	27 Oct 2020 20:32:48

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-10-27T15:32:17', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd69f9f16-86b2-4ef1-aa40-3a556b3fd2ea'	System	27 Oct 2020 20:32:48
User entered 'No (N)'	System	27 Oct 2020 20:32:48

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-10-27T15:32:20', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd69f9f16-86b2-4ef1-aa40-3a556b3fd2ea'	System	27 Oct 2020 20:32:48
User entered '27 Oct 2020 15:32:20'	System	27 Oct 2020 20:32:48

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered '25 Oct 2020 00:01'	System	25 Aug 2020 21:45:17

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered '29 Oct 2020 23:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 71'	System	25 Aug 2020 21:45:17

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-03T15:37:04', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '65380f4e-a86d-4ecc-9908-f44c1f5d09fd'	System	03 Nov 2020 21:37:31
User entered 'Yes (Y)'	System	03 Nov 2020 21:37:31

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-03T15:37:08', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '65380f4e-a86d-4ecc-9908-f44c1f5d09fd'	System	03 Nov 2020 21:37:31
User entered 'No (N)'	System	03 Nov 2020 21:37:31

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-03T15:37:11', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '65380f4e-a86d-4ecc-9908-f44c1f5d09fd'	System	03 Nov 2020 21:37:31
User entered 'No (N)'	System	03 Nov 2020 21:37:31

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-03T15:37:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '65380f4e-a86d-4ecc-9908-f44c1f5d09fd'	System	03 Nov 2020 21:37:31
User entered 'No (N)'	System	03 Nov 2020 21:37:31

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Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-03T15:37:27', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '65380f4e-a86d-4ecc-9908-f44c1f5d09fd'	System	03 Nov 2020 21:37:31
User entered '03 Nov 2020 15:37:27'	System	03 Nov 2020 21:37:31

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered '01 Nov 2020 00:01'	System	25 Aug 2020 21:45:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered '05 Nov 2020 23:59'	System	25 Aug 2020 21:45:17

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Folder: Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered 'Day 78'	System	25 Aug 2020 21:45:17

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-09T10:02:17', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '83d2b93b-f3e9-43b7-9b9c-3b1fca7a3665'	System	09 Nov 2020 16:02:27
User entered 'No (N)'	System	09 Nov 2020 16:02:27

1b

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-09T10:02:20', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '83d2b93b-f3e9-43b7-9b9c-3b1fca7a3665'	System	09 Nov 2020 16:02:27
User entered 'No (N)'	System	09 Nov 2020 16:02:27

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-09T10:02:23', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '83d2b93b-f3e9-43b7-9b9c-3b1fca7a3665'	System	09 Nov 2020 16:02:27
User entered '09 Nov 2020 10:02:23'	System	09 Nov 2020 16:02:27

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered '08 Nov 2020 00:01'	System	25 Aug 2020 21:45:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
Data entry locked.	System	25 Aug 2020 21:45:17
User entered '12 Nov 2020 23:59'	System	25 Aug 2020 21:45:17

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 14:59:41
Amendment Manager: DataPoint Inactivated.	(b) (4)	
Data entry locked.	System	19 Nov 2020 17:44:32
User entered 'Day 92'	System	25 Aug 2020 21:45:17
	System	25 Aug 2020 21:45:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-24T14:23:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '70097d50-0c1e-4f74-bf0d-40f167c1cfef'	System	24 Nov 2020 20:23:50
User entered 'No (N)'	System	24 Nov 2020 20:23:50
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 14:59:41
Amendment Manager: DataPoint Inactivated.	(b) (4)	
	System	19 Nov 2020 17:44:32

US3292316

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-24T14:23:37', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '70097d50-0c1e-4f74-bf0d-40f167c1cfef'	System	24 Nov 2020 20:23:50
User entered 'No (N)'	System	24 Nov 2020 20:23:50
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 14:59:41
Amendment Manager: DataPoint Inactivated.	(b) (4)	
	System	19 Nov 2020 17:44:32

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Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-24T14:23:46', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '70097d50-0c1e-4f74-bf0d-40f167c1cfef'	System	24 Nov 2020 20:23:50
User entered '24 Nov 2020 14:23:46'	System	24 Nov 2020 20:23:50
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 14:59:41
Amendment Manager: DataPoint Inactivated.	(b) (4)	
	System	19 Nov 2020 17:44:32

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 14:59:41
Amendment Manager: DataPoint Inactivated.	(b) (4)	
Data entry locked.	System	19 Nov 2020 17:44:32
User entered '22 Nov 2020 00:01'	System	25 Aug 2020 21:45:17
	System	25 Aug 2020 21:45:17

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	05 Mar 2021 00:17:36
DataPoint activated with code reason code Data required.	Nolan Payton (b) (4)	24 Nov 2020 14:59:41
Amendment Manager: DataPoint Inactivated.	(b) (4)	
Data entry locked.	System	19 Nov 2020 17:44:32
User entered '26 Nov 2020 23:59'	System	25 Aug 2020 21:45:17
	System	25 Aug 2020 21:45:17

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 89'	System	19 Nov 2020 17:44:32

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 96'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-29T15:48:46', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2f9ee120-7ae1-43a6-bfa9-f7cfbf4f1140'	System	29 Nov 2020 21:48:55
User entered 'No (N)'	System	29 Nov 2020 21:48:55

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Folder: New Safety Follow Up Diary (1)

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[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2020-11-29T15:48:48', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2f9ee120-7ae1-43a6-bfa9-f7cfbf4f1140'	System	29 Nov 2020 21:48:55
User entered 'No (N)'	System	29 Nov 2020 21:48:55

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-11-29T15:48:52', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2f9ee120-7ae1-43a6-bfa9-f7cfbf4f1140'	System	29 Nov 2020 21:48:55
User entered '29 Nov 2020 15:48:52'	System	29 Nov 2020 21:48:55

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 103'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-03T00:25:53', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bfde537b-62df-4d33-8123-1da82507a8a2'	System	03 Dec 2020 06:26:02
User entered 'No (N)'	System	03 Dec 2020 06:26:02

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[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2020-12-03T00:25:56', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bfde537b-62df-4d33-8123-1da82507a8a2'	System	03 Dec 2020 06:26:02
User entered 'No (N)'	System	03 Dec 2020 06:26:02

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-03T00:25:58', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'bfde537b-62df-4d33-8123-1da82507a8a2'	System	03 Dec 2020 06:26:02
User entered '03 Dec 2020 00:25:58'	System	03 Dec 2020 06:26:02

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 17:44:32

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-10T03:53:30', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '485827a8-2bc0-49d8-88b4-834aba5051c7'	System	10 Dec 2020 09:53:43
User entered 'No (N)'	System	10 Dec 2020 09:53:43

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Folder: New Safety Follow Up Diary (1)

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[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2020-12-10T03:53:37', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '485827a8-2bc0-49d8-88b4-834aba5051c7'	System	10 Dec 2020 09:53:43
User entered 'No (N)'	System	10 Dec 2020 09:53:43

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-10T03:53:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '485827a8-2bc0-49d8-88b4-834aba5051c7'	System	10 Dec 2020 09:53:43
User entered '10 Dec 2020 03:53:39'	System	10 Dec 2020 09:53:43

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 17:44:32

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-17T15:46:03', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ac529507-b65b-48ee-9926-0b2b4461db49'	System	17 Dec 2020 21:46:38
User entered 'Yes (Y)'	System	17 Dec 2020 21:46:38

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Folder: New Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2020-12-17T15:45:55', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ac529507-b65b-48ee-9926-0b2b4461db49'	System	17 Dec 2020 21:46:38
User entered 'Yes (Y)'	System	17 Dec 2020 21:46:38

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Folder: New Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-17T15:45:50', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ac529507-b65b-48ee-9926-0b2b4461db49'	System	17 Dec 2020 21:46:38
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	17 Dec 2020 21:46:38

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[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-17T15:46:12', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ac529507-b65b-48ee-9926-0b2b4461db49'	System	17 Dec 2020 21:46:38
User entered 'No (N)'	System	17 Dec 2020 21:46:38

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Folder: New Safety Follow Up Diary (1)

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[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 (14cc61ffb83fe4de)', Time: '2020-12-17T15:46:17', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ac529507-b65b-48ee-9926-0b2b4461db49'	System	17 Dec 2020 21:46:38
User entered 'No (N)'	System	17 Dec 2020 21:46:38

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Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-17T15:46:27', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ac529507-b65b-48ee-9926-0b2b4461db49'	System	17 Dec 2020 21:46:38
User entered '17 Dec 2020 15:46:27'	System	17 Dec 2020 21:46:38

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 17:44:32

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Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2020-12-26T12:21:20', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5bcebfc7-0272-4b85-bad8-10c1c3bc93f9'	System	26 Dec 2020 18:21:30
User entered 'No (N)'	System	26 Dec 2020 18:21:30

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2020-12-26T12:21:23', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5bcebfc7-0272-4b85-bad8-10c1c3bc93f9'	System	26 Dec 2020 18:21:30
User entered 'No (N)'	System	26 Dec 2020 18:21:30

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-26T12:21:26', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5bcebfc7-0272-4b85-bad8-10c1c3bc93f9'	System	26 Dec 2020 18:21:30
User entered '26 Dec 2020 12:21:26'	System	26 Dec 2020 18:21:30

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2020-12-31T20:00:39', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e7507e9b-6871-43c4-8ad0-35af13f41935'	System	01 Jan 2021 02:00:51
User entered 'No (N)'	System	01 Jan 2021 02:00:51

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2020-12-31T20:00:42', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e7507e9b-6871-43c4-8ad0-35af13f41935'	System	01 Jan 2021 02:00:51
User entered 'No (N)'	System	01 Jan 2021 02:00:51

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2020-12-31T20:00:45', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e7507e9b-6871-43c4-8ad0-35af13f41935'	System	01 Jan 2021 02:00:51
User entered '31 Dec 2020 20:00:45'	System	01 Jan 2021 02:00:51

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-01-08T07:32:48', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '87ba6dff-936b-4067-a057-3087ecf69019'	System	08 Jan 2021 13:33:41
User entered 'Yes (Y)'	System	08 Jan 2021 13:33:41

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-01-08T07:32:52', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '87ba6dff-936b-4067-a057-3087ecf69019'	System	08 Jan 2021 13:33:41
User entered 'No (N)'	System	08 Jan 2021 13:33:41

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-01-08T07:33:17', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '87ba6dff-936b-4067-a057-3087ecf69019'	System	08 Jan 2021 13:33:41
User entered 'No (N)'	System	08 Jan 2021 13:33:41

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-01-08T07:33:31', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '87ba6dff-936b-4067-a057-3087ecf69019'	System	08 Jan 2021 13:33:41
User entered 'No (N)'	System	08 Jan 2021 13:33:41

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-01-08T07:33:35', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '87ba6dff-936b-4067-a057-3087ecf69019' User entered '08 Jan 2021 07:33:35'	System	08 Jan 2021 13:33:41

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-01-15T12:55:06', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '478fe1c9-4ab1-4994-ad3f-147aa4c6eb7e'	System	15 Jan 2021 18:55:44
User entered 'Yes (Y)'	System	15 Jan 2021 18:55:44

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-01-15T12:55:16', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '478fe1c9-4ab1-4994-ad3f-147aa4c6eb7e'	System	15 Jan 2021 18:55:44
User entered 'No (N)'	System	15 Jan 2021 18:55:44

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-01-15T12:55:18', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '478fe1c9-4ab1-4994-ad3f-147aa4c6eb7e'	System	15 Jan 2021 18:55:44
User entered 'No (N)'	System	15 Jan 2021 18:55:44

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-01-15T12:55:27', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '478fe1c9-4ab1-4994-ad3f-147aa4c6eb7e'	System	15 Jan 2021 18:55:44
User entered 'Yes (Y)'	System	15 Jan 2021 18:55:44

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Please 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 (14cc61ffb83fe4de)', Time: '2021-01-15T12:55:31', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '478fe1c9-4ab1-4994-ad3f-147aa4c6eb7e'	System	15 Jan 2021 18:55:44
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	15 Jan 2021 18:55:44

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-01-15T12:55:34', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '478fe1c9-4ab1-4994-ad3f-147aa4c6eb7e' User entered '15 Jan 2021 12:55:34'	System	15 Jan 2021 18:55:44

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-01-21T12:39:41', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '45ef1344-0724-4781-8995-7fab9e47602f'	System	21 Jan 2021 18:39:48
User entered 'No (N)'	System	21 Jan 2021 18:39:48

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-01-21T12:39:44', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '45ef1344-0724-4781-8995-7fab9e47602f'	System	21 Jan 2021 18:39:48
User entered 'No (N)'	System	21 Jan 2021 18:39:48

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-01-21T12:39:46', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '45ef1344-0724-4781-8995-7fab9e47602f' User entered '21 Jan 2021 12:39:46'	System	21 Jan 2021 18:39:48

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-01-30T00:42:43', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'aa2728bf-8caf-4328-80cd-1bf0207948c6'	System	30 Jan 2021 06:42:53
User entered 'No (N)'	System	30 Jan 2021 06:42:53

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-01-30T00:42:45', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'aa2728bf-8caf-4328-80cd-1bf0207948c6'	System	30 Jan 2021 06:42:53
User entered 'No (N)'	System	30 Jan 2021 06:42:53

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-01-30T00:42:49', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'aa2728bf-8caf-4328-80cd-1bf0207948c6'	System	30 Jan 2021 06:42:53
User entered '30 Jan 2021 00:42:49'	System	30 Jan 2021 06:42:53

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-02-04T04:55:44', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c6dc5e3-870f-4d08-a20d-c780ce1361c8'	System	04 Feb 2021 10:55:53
User entered 'No (N)'	System	04 Feb 2021 10:55:53

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-02-04T04:55:47', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c6dc5e3-870f-4d08-a20d-c780ce1361c8'	System	04 Feb 2021 10:55:53
User entered 'No (N)'	System	04 Feb 2021 10:55:53

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-02-04T04:55:48', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '2c6dc5e3-870f-4d08-a20d-c780ce1361c8' User entered '04 Feb 2021 04:55:48'	System	04 Feb 2021 10:55:53

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-02-11T00:04:30', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5912721a-3e4d-414f-bd63-e72e9b03f0d8'	System	11 Feb 2021 06:04:39
User entered 'No (N)'	System	11 Feb 2021 06:04:39

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-02-11T00:04:32', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5912721a-3e4d-414f-bd63-e72e9b03f0d8'	System	11 Feb 2021 06:04:39
User entered 'No (N)'	System	11 Feb 2021 06:04:39

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-02-11T00:04:35', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '5912721a-3e4d-414f-bd63-e72e9b03f0d8'	System	11 Feb 2021 06:04:39
User entered '11 Feb 2021 00:04:35'	System	11 Feb 2021 06:04:39

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-02-20T05:07:42', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'b902036e-a5d7-41aa-8e38-3d4282b16b4d'	System	20 Feb 2021 11:07:50
User entered 'No (N)'	System	20 Feb 2021 11:07:50

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-02-20T05:07:44', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'b902036e-a5d7-41aa-8e38-3d4282b16b4d'	System	20 Feb 2021 11:07:50
User entered 'No (N)'	System	20 Feb 2021 11:07:50

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-02-20T05:07:47', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'b902036e-a5d7-41aa-8e38-3d4282b16b4d'	System	20 Feb 2021 11:07:50
User entered '20 Feb 2021 05:07:47'	System	20 Feb 2021 11:07:50

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-02-25T20:01:29-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ca674be3-6d3c-42fd-ab17-7dfc47538abb' User entered 'No (N)'	System	26 Feb 2021 02:05:54

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-02-25T20:01:33-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ca674be3-6d3c-42fd-ab17-7dfc47538abb' User entered 'No (N)'	System	26 Feb 2021 02:05:54

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-02-25T20:01:35-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'ca674be3-6d3c-42fd-ab17-7dfc47538abb' User entered '25 Feb 2021 20:01:35'	System	26 Feb 2021 02:05:54

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-03-04T00:40:45-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '73e06d9c-2e16-402c-a12b-9b2def46eed7'	System	04 Mar 2021 06:40:57
User entered 'No (N)'	System	04 Mar 2021 06:40:57

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-03-04T00:40:48-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '73e06d9c-2e16-402c-a12b-9b2def46eed7'	System	04 Mar 2021 06:40:57
User entered 'No (N)'	System	04 Mar 2021 06:40:57

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-03-04T00:40:52-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '73e06d9c-2e16-402c-a12b-9b2def46eed7'	System	04 Mar 2021 06:40:57
User entered '04 Mar 2021 00:40:52'	System	04 Mar 2021 06:40:57

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-03-11T20:00:38-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '9085a04c-4a26-4dec-a2f0-6e10e40b7afc'	System	12 Mar 2021 02:02:10
User entered 'No (N)'	System	12 Mar 2021 02:02:10

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-03-11T20:00:40-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '9085a04c-4a26-4dec-a2f0-6e10e40b7afc'	System	12 Mar 2021 02:02:10
User entered 'No (N)'	System	12 Mar 2021 02:02:10

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-03-11T20:00:43-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '9085a04c-4a26-4dec-a2f0-6e10e40b7afc' User entered '11 Mar 2021 20:00:43'	System	12 Mar 2021 02:02:10

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-03-20T15:25:17-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '05a869f6-fc66-4b5a-8420-0a5c4e2f9c9c'	System	20 Mar 2021 20:25:25
User entered 'No (N)'	System	20 Mar 2021 20:25:25

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-03-20T15:25:20-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '05a869f6-fc66-4b5a-8420-0a5c4e2f9c9c'	System	20 Mar 2021 20:25:25
User entered 'No (N)'	System	20 Mar 2021 20:25:25

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-03-20T15:25:23-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '05a869f6-fc66-4b5a-8420-0a5c4e2f9c9c' User entered '20 Mar 2021 15:25:23'	System	20 Mar 2021 20:25:25
	System	20 Mar 2021 20:25:25

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-03-26T14:41:45-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd88deb7e-d410-40e3-b010-253b50620ffa' User entered 'No (N)'	System	26 Mar 2021 19:41:54
	System	26 Mar 2021 19:41:54

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-03-26T14:41:47-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd88deb7e-d410-40e3-b010-253b50620ffa' User entered 'No (N)'	System	26 Mar 2021 19:41:54

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-03-26T14:41:50-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'd88deb7e-d410-40e3-b010-253b50620ffa' User entered '26 Mar 2021 14:41:50'	System	26 Mar 2021 19:41:54
	System	26 Mar 2021 19:41:54

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-04-01T01:07:28-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '40d61581-8697-4f34-8e1c-2e621f9925b8' User entered 'No (N)'	System	01 Apr 2021 06:07:36
	System	01 Apr 2021 06:07:36

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-04-01T01:07:30-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '40d61581-8697-4f34-8e1c-2e621f9925b8'	System	01 Apr 2021 06:07:36
User entered 'No (N)'	System	01 Apr 2021 06:07:36

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-04-01T01:07:32-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '40d61581-8697-4f34-8e1c-2e621f9925b8' User entered '01 Apr 2021 01:07:32'	System	01 Apr 2021 06:07:36
	System	01 Apr 2021 06:07:36

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-04-09T00:32:46-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e03e0b82-df75-477a-a2b3-05792c5b0cdd' User entered 'No (N)'	System	09 Apr 2021 05:32:51

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-04-09T00:32:47-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e03e0b82-df75-477a-a2b3-05792c5b0cdd' User entered 'No (N)'	System	09 Apr 2021 05:32:51

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-04-09T00:32:50-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e03e0b82-df75-477a-a2b3-05792c5b0cdd' User entered '09 Apr 2021 00:32:50'	System	09 Apr 2021 05:32:51
	System	09 Apr 2021 05:32:51

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-04-15T07:14:04-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '56e1127e-983f-41d4-8986-c01f6cfee94d' User entered 'No (N)'	System	15 Apr 2021 12:14:10
	System	15 Apr 2021 12:14:10

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-04-15T07:14:05-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '56e1127e-983f-41d4-8986-c01f6cfee94d' User entered 'No (N)'	System	15 Apr 2021 12:14:10
	System	15 Apr 2021 12:14:10

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-04-15T07:14:09-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '56e1127e-983f-41d4-8986-c01f6cfee94d' User entered '15 Apr 2021 07:14:09'	System	15 Apr 2021 12:14:10
	System	15 Apr 2021 12:14:10

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-04-22T00:01:45-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e0a5946a-b800-448e-b8ae-e8c514a82366'	System	22 Apr 2021 05:01:58
User entered 'No (N)'	System	22 Apr 2021 05:01:58

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-04-22T00:01:49-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e0a5946a-b800-448e-b8ae-e8c514a82366'	System	22 Apr 2021 05:01:58
User entered 'No (N)'	System	22 Apr 2021 05:01:58

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-04-22T00:01:54-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'e0a5946a-b800-448e-b8ae-e8c514a82366' User entered '22 Apr 2021 00:01:54'	System	22 Apr 2021 05:01:58
	System	22 Apr 2021 05:01:58

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[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 (14cc61ffb83fe4de)', Time: '2021-05-01T20:05:40-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'f69235d2-4c46-4fe2-8e0f-3b53750e3350'	System	02 May 2021 01:11:16
User entered 'No (N)'	System	02 May 2021 01:11:16

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Have you been exposed to someone with 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 (14cc61ffb83fe4de)', Time: '2021-05-01T20:05:42-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'f69235d2-4c46-4fe2-8e0f-3b53750e3350'	System	02 May 2021 01:11:16
User entered 'No (N)'	System	02 May 2021 01:11:16

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-05-01T20:05:44-05:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: 'f69235d2-4c46-4fe2-8e0f-3b53750e3350'	System	02 May 2021 01:11:16
User entered '01 May 2021 20:05:44'	System	02 May 2021 01:11:16

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[New loss of taste](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[New loss of smell](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Sore throat](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Congestion](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Runny nose](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
User entered '0'	(b) (4), (b) (6)	03 May 2021 15:28:45

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 17:44:32

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Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '13 Oct 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '17 Oct 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '20 Oct 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '24 Oct 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '27 Oct 2022 00:01'	System	19 Nov 2020 17:44:32

US3292316

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 16:31:58

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 17:44:32
Amendment Manager: User entered '31 Oct 2022 23:59'	System	19 Nov 2020 17:44:32

US3292316

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:31:58

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:07:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-03-02T01:02:53-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '37beccf0-4984-430c-9803-067e3f2346c5'	System	02 Mar 2021 07:02:59
User entered 'No (N)'	System	02 Mar 2021 07:02:59

US3292316

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 16:31:58

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:07:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (14cc61ffb83fe4de)', Time: '2021-03-02T01:02:56-06:00', User OID: 'PatientReportedOutcome (US3292316)', ODM File OID: '37beccf0-4984-430c-9803-067e3f2346c5' User entered '02 Mar 2021 01:02:56'	System	02 Mar 2021 07:02:59
	System	02 Mar 2021 07:02:59

US3292316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
DataPoint Verified.		16 Mar 2021 14:03:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:15:56

US3292316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
DataPoint Verified.		16 Mar 2021 14:03:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '17 Nov 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:15:56

US3292316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
DataPoint Verified.		16 Mar 2021 14:03:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:15:56

US3292316

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
DataPoint Verified.		16 Mar 2021 14:03:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:15:56

US3292316

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
DataPoint Verified.		16 Mar 2021 14:04:13
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:16:08

US3292316

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Mar 2021 02:40:46
User entered 'l'	System	19 Nov 2020 22:16:08

US3292316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:06:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:36

US3292316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:06:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:36

US3292316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:06:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:36

US3292316

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:06:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:36

US3292316

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:08:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:42

US3292316

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
User entered 'l'	System	25 Jan 2021 19:02:42

US3292316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:08:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:57

US3292316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:08:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '21 Jan 2021'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:57

US3292316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:08:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:57

US3292316

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:08:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:02:57

US3292316

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:09:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Jan 2021 19:03:11

US3292316

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
User entered 'l'	System	25 Jan 2021 19:03:11

US3292316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:09:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:29:01

US3292316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:09:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:29:01

US3292316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:09:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:29:01

US3292316

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.		16 Mar 2021 14:09:18
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:29:01

US3292316

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 14:09:38
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Feb 2021 01:29:09

US3292316

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	15 Apr 2021 04:50:37
User entered 'l'	System	20 Feb 2021 01:29:09

US3292316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:34
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:24:46

US3292316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:34
User entered '19 Mar 2021'	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:24:46

US3292316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:34
User entered 'Clinic (Clinic)'	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:24:46

US3292316

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'VISIT4'	System	19 Mar 2021 19:24:46

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered 'No (N)'		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:39
User entered empty.		31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered empty.	System	31 Mar 2021 19:26:32

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44

US3292316

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44

US3292316

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:48
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:24:49

US3292316

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:48
User entered empty.	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:24:49

US3292316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:55
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:25:34

US3292316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:55
User entered '19 Mar 2021'	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:25:34

US3292316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:40:55
User entered '09:55'	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:25:34

US3292316

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered '19 Mar 2021 09:55'	System	19 Mar 2021 19:25:34

US3292316

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 16:41:04
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	19 Mar 2021 19:25:37

US3292316

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 18:22:44
User entered 'I'	System	19 Mar 2021 19:25:37

US3292316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:40:25
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4)	26 Apr 2021 14:07:13

US3292316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:40:25
User entered '20 Apr 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Apr 2021 14:07:13

US3292316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:40:25
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Apr 2021 14:07:13

US3292316

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 16:31:58

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:40:25
User entered empty.	(b) (4) Gerardo Pena (b) (4)	26 Apr 2021 14:07:13

US3292316

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:40:25
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	26 Apr 2021 14:14:09

US3292316

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 16:31:58

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	26 Apr 2021 14:14:09

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:31:58

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:30:55
DataPoint Verified.	(b) (4)	08 Apr 2021 19:07:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 15-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 15-DEC-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Covid Diagnostic Test eCRF, else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 12:00:59
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 15-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 15-DEC-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Covid Diagnostic Test eCRF, else clarify. ' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	20 Feb 2021 00:30:02
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 15-DEC-2020 is reported under Illness Visit Day 1 in PPD portal; however, swab sample for 15-DEC-2020 is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Covid Diagnostic Test eCRF, else clarify. ' (Site from DM).	(b) (4), (b) (6)	22 Dec 2020 06:03:49
User entered '14 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:14:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:31:58

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:30:55
DataPoint Verified.		08 Apr 2021 19:07:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '15:05'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:14:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:31:58

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:30:55
User entered '14 Dec 2020 15:05'	System	17 Dec 2020 18:14:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:31:58

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:30:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:07:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Safety Call (Safety Call)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:14:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 16:31:58

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:30:55
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:07:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:14:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Day 1 (Day 1)'	(b) (4) Gerardo Pena (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4)	
	Gerardo Pena (b) (4)	17 Dec 2020 18:18:09
User entered '14 Dec 2020'	(b) (4)	
	Gerardo Pena (b) (4)	17 Dec 2020 18:17:46
	(b) (4)	

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User closed query 'Per CDM: It appears that O2 Saturation & Temperature for Day 1 – Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 10:01:25
Query 'Per CDM: It appears that O2 Saturation & Temperature for Day 1 – Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' answered with 'COMPLETED' (Site from DM).	(b) (4), (b) (6)	25 Jan 2021 19:51:28
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:51:14
User opened query 'Per CDM: It appears that O2 Saturation & Temperature for Day 1 – Day 3 were not provided. If not collected, please consider recording as 'Not Done'. Thank you.' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 08:46:57
User entered empty.	Gerardo Pena (b) (4)	17 Dec 2020 18:17:46

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	25 Jan 2021 19:51:14
User entered empty.	System	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:51:14
User entered empty.	Gerardo Pena (b) (4)	17 Dec 2020 18:17:46
	(b) (4)	

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:17:46

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Mild (Mild)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Dec 2020 18:28:10
User entered empty.	(b) (4)	
	Gerardo Pena (b) (4)	17 Dec 2020 18:17:46
	(b) (4)	

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Day 2 (Day 2)'	(b) (4) Gerardo Pena (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '13 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:51:14
User entered empty.	Gerardo Pena (b) (4)	17 Dec 2020 18:18:36

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	25 Jan 2021 19:51:14
User entered empty.	System	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:51:14
User entered empty.	Gerardo Pena (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:36

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:09:45
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Mild (Mild)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Dec 2020 18:28:19
User entered empty.	(b) (4)	
	Gerardo Pena (b) (4)	17 Dec 2020 18:18:36
	(b) (4)	

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Day 3 (Day 3)'	(b) (4) Gerardo Pena (b) (4)	17 Dec 2020 18:18:56

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '14 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:51:14
User entered empty.	Gerardo Pena (b) (4)	17 Dec 2020 18:18:56
	(b) (4)	

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	25 Jan 2021 19:51:14
User entered empty.	System	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:51:14
User entered empty.	Gerardo Pena (b) (4)	17 Dec 2020 18:18:56
	(b) (4)	

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Mild (Mild)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:18:56

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:09:48
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Mild (Mild)' reason for change: New Information	(b) (4)	
	Gerardo Pena (b) (4)	17 Dec 2020 18:28:35
User entered empty.	(b) (4)	
	Gerardo Pena (b) (4)	17 Dec 2020 18:18:56
	(b) (4)	

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Day 4 (Day 4)'	(b) (4) Gerardo Pena (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:57:55
User entered '15 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:09:52
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '0'	(b) (4) Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:57:58
User entered '98'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:00
User entered '38.2' C	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:14
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:26
User entered 'Mild (Mild)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:29
User entered 'Moderate (Moderate)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:39
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:41
User entered 'Moderate (Moderate)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:43
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:45
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:50
User entered 'Moderate (Moderate)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:54
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:57
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:58:59
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:03
User entered 'Moderate (Moderate)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:05
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:07
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:09
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:11
User entered 'Mild (Mild)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:21:37

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Day 5 (Day 5)'	(b) (4) Gerardo Pena (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:28
User entered '16 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:30
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:32
User entered '95'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:34
User entered '36.2' C	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:00:04
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:46
User entered 'Mild (Mild)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:00:07
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:00:10
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:48
User entered 'Mild (Mild)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:00:19
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:01
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:03
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:05
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:07
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:59:54
User entered 'Mild (Mild)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:09
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:11
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:12
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:14
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:01:15
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:56:30

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User closed query 'Please Provide source' (Site from CRA).	(b) (4)	08 Apr 2021 19:13:13
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Query 'Please Provide source' answered with 'eSource is provided' (Site from CRA).	(b) (4)	(b) (4)
User opened query 'Please Provide source' (Site from CRA).	(b) (4), (b) (6)	18 Feb 2021 01:04:47
User entered 'Day 6 (Day 6)'	(b) (4), (b) (6)	08 Feb 2021 19:02:51
	(b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '17 Dec 2020'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '0'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '95'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '36.2' C	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Mild (Mild)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:16:05
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	18 Dec 2020 16:29:51

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User closed query 'Per CDM RQ: day 7 missing on symptom log, please clarify ' (Site from DM).	(b) (4)	16 Apr 2021 16:57:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4)	
Query 'Per CDM RQ: day 7 missing on symptom log, please clarify ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	15 Apr 2021 15:18:58
User opened query 'Per CDM RQ: day 7 missing on symptom log, please clarify ' (Site from DM).	Antonio Gutierrez (b) (4)	15 Apr 2021 15:18:11
User closed query 'per CDM: day 7 missing on symptom log, please clarify ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 13:09:37
Query 'per CDM: day 7 missing on symptom log, please clarify ' answered with 'Updated ' (Site from DM).	(b) (4), (b) (6)	15 Apr 2021 13:09:37
Signature has been broken.	(b) (4), (b) (6)	14 Apr 2021 01:34:01
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	(b) (4), (b) (6)	14 Apr 2021 01:33:40
User opened query 'per CDM: day 7 missing on symptom log, please clarify ' (Site from DM).	(b) (4), (b) (6)	14 Apr 2021 01:33:40
User signature succeeded.	Douglas Denham (b) (4)	15 Mar 2021 23:44:32
User entered 'Day 8 (Day 8)'	(b) (4)	23 Feb 2021 14:12:24
	(b) (4), (b) (6)	20 Dec 2020 15:13:20

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:16
User entered '19 Dec 2020'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:18
User entered '0'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:22
User entered '96'		20 Dec 2020 15:13:20

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	20 Dec 2020 15:13:20

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Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:20
User entered '36.2' C		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	08 Feb 2021 19:08:30
User entered 'None (None)'	(b) (4), (b) (6)	20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:32
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:35
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:38
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:39
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:41
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:42
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:44
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:45
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:47
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4)	08 Feb 2021 19:08:48
User entered 'None (None)'	(b) (4), (b) (6)	20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:49
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:51
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:52
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:53
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:08:55
User entered 'None (None)'		20 Dec 2020 15:13:20

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'Day 9 (Day 9)'	(b) (4) Gerardo Pena (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:15
User entered '20 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:16
User entered '0'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:18
User entered '96'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:19
User entered '36.6' C	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:21
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:22
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:24
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:26
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:32
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:35
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:36
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:38
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:40
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:41
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:43
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:44
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:46
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:47
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:50
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 19:09:51
User entered 'None (None)'	Gerardo Pena (b) (4) (b) (4)	21 Dec 2020 15:16:33

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
Signature has been broken.	(b) (4)	
	Antonio Gutierrez (b) (4)	15 Apr 2021 15:19:13
User entered 'Day 10 (Day 10)' reason for change:	Antonio Gutierrez (b) (4)	15 Apr 2021 15:19:13
Data Entry Error	(b) (4)	
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered 'Day 22 (Day 22)'	(b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '0'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '98'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '36.8' C	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4)	08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		08 Apr 2021 19:15:50
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'None (None)'	(b) (4) (b) (4), (b) (6)	22 Dec 2020 22:14:46

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'Day 7 (Day 7)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered '18 Dec 2020'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered '0'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered '94'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
User entered '%'	System	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered '36.9' C	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'Mild (Mild)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'Mild (Mild)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'None (None)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Symptom Log (10)

Generated On: 09 Jun 2021 16:31:58

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:01
DataPoint Verified.		19 Apr 2021 18:49:00
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'Mild (Mild)'	(b) (4) Antonio Gutierrez (b) (4)	15 Apr 2021 15:17:58

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered '15 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.		08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.		08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.		08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered '15 Dec 2020'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[Type of Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.		08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.		08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.		08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.		08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered empty.	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
DataPoint Verified.		08 Apr 2021 19:08:16
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered empty.	(b) (4)	
	Gerardo Pena (b) (4)	28 Jan 2021 17:56:12
	(b) (4)	

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 16:31:58

COVID-19 Positive (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:07
User entered '0'	System	28 Jan 2021 17:56:12

US3292316

Folder: Covid-19 Assessment 14 Dec 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 16:31:58

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:31:13
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:08:23
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'No (N)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	28 Jan 2021 17:56:18

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:31:58

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User accepted default value 'Day 3 (Day 3)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:31:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:36:11
User entered 'Yes (Y)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 16:31:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4), (b) (6)	08 Feb 2021 18:36:13
User entered '17 Dec 2020'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:31:58

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User accepted default value 'Day 5 (Day 5)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:31:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:36:49
User entered 'Yes (Y)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 16:31:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:36:51
User entered '19 Dec 2020'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:31:58

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User accepted default value 'Day 7 (Day 7)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:31:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User closed query 'please Provide source' (Site from CRA).	(b) (4), (b) (6)	08 Apr 2021 19:23:49
DataPoint Verified.		08 Apr 2021 19:23:37
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Query 'please Provide source' answered with 'Assession #1F60BVG' (Site from CRA).	(b) (4)	(b) (4)
User opened query 'please Provide source' (Site from CRA).	(b) (4), (b) (6)	17 Feb 2021 23:45:39
User entered 'Yes (Y)'	(b) (4), (b) (6)	08 Feb 2021 18:37:20
		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 16:31:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.		08 Apr 2021 19:23:39
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '21 Dec 2020'	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:31:58

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User accepted default value 'Day 9 (Day 9)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:31:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:24:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 21:30:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:30:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:30:17
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 16:55:30
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 16:31:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.		08 Apr 2021 19:24:24
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:31:58

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User accepted default value 'Day 14 (Day 14)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:31:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.	(b) (4)	08 Apr 2021 19:24:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 21:30:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:30:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:30:17
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 16:55:30
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 16:31:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.		08 Apr 2021 19:24:25
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:31:58

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User accepted default value 'Day 21 (Day 21)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:31:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.	(b) (4)	08 Apr 2021 19:24:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 21:30:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:30:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:30:17
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 16:55:30
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 16:31:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.		08 Apr 2021 19:24:28
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:31:58

[Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
User accepted default value 'Day 28 (Day 28)'		07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:31:58

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.	(b) (4)	08 Apr 2021 19:24:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	25 Jan 2021 21:30:17
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 21:30:17
User entered 'NA (COVID-19 Negative) (NA)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 21:30:17
User opened query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 16:55:30
User entered empty.	(b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 16:31:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:08
DataPoint Verified.		08 Apr 2021 19:24:30
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered empty.	(b) (4) (b) (4), (b) (6)	07 Jan 2021 16:55:30

US3292316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19DEC2020 is reported under Illness Visit Day 5, 21DEC2020 is reported under Illness Visit Day 7 , however they are missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' canceled (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	12 Feb 2021 07:41:26
		08 Feb 2021 18:40:00
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 19DEC2020 is reported under Illness Visit Day 5, 21DEC2020 is reported under Illness Visit Day 7 , however they are missing in EDC. Please review if the sample has been collected then update the details under appropriate visit.' (Site from DM).		30 Dec 2020 13:04:26
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:51:48

US3292316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' canceled (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	12 Feb 2021 07:41:28
User opened query 'Per GCL Lab Reconciliation: Saliva : Sample dated 17DEC2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM). User entered '15 Dec 2020'	Gerardo Pena (b) (4)	17 Dec 2020 18:51:48
	(b) (4)	08 Feb 2021 18:40:05
		24 Dec 2020 08:21:42

US3292316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:49
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:40:07
User entered 'Home (Home)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:51:48

US3292316

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:49
User entered 'SICKD1'	System	17 Dec 2020 18:51:48

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:40:25
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 19:37:43
DataPoint Un-verified.		08 Feb 2021 18:40:45
DataPoint Verified.		08 Feb 2021 18:40:28
User entered '15 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:40:47
User entered '12:32'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User entered '15 Dec 2020 12:32'	System	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:40:37
User entered '165.1' cm	Gerardo Pena (b) (4)	17 Dec 2020 18:53:51
DataPoint set to visible.	(b) (4) System	17 Dec 2020 18:51:48

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	08 Feb 2021 18:42:05
DataPoint Un-verified.	(b) (4), (b) (6)	08 Feb 2021 18:41:36
DataPoint Verified.		08 Feb 2021 18:40:39
User entered '76.24' kg	Gerardo Pena (b) (4)	17 Dec 2020 18:53:51
DataPoint set to visible.	(b) (4) System	17 Dec 2020 18:51:48

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Please confirm with source.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:11:22
		08 Apr 2021 19:11:18
Query 'Please confirm with source.' answered with 'updated as per source ' (Site from CRA).	Antonio Gutierrez (b) (4)	08 Mar 2021 21:57:26
User entered '38.22' C reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	08 Mar 2021 21:57:08
User opened query 'Please confirm with source.' (Site from CRA).	(b) (4), (b) (6)	08 Feb 2021 18:42:02
User entered '38.2' C	Gerardo Pena (b) (4)	17 Dec 2020 18:53:51
	(b) (4)	

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:42:11
User entered 'Oral (Oral)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:42:13
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:42:19
User entered '79'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User entered 'bpm'	System	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:42:21
User entered '17'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User entered 'breaths/min'	System	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:42:22
User entered '138'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User entered 'mmHg'	System	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:42:24
User entered '75'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55
User entered 'mmHg'	System	17 Dec 2020 18:53:51

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55

US3292316

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 16:31:58

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:55

US3292316

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:59
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:42:34
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:54:24

US3292316

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 16:31:58

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:48:59
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:42:34
User entered '15 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:54:24

US3292316

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:31:58

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:43:27
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:54:36

US3292316

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 16:31:58

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:49:02
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 18:43:27
User entered '15 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:54:36

US3292316

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

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:44:06
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:03

US3292316

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

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:44:06
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered '4 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:03

US3292316

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

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[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 16:28:54
DataPoint Verified.		08 Apr 2021 19:44:06
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered 'Clinic (Clinic)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:03

US3292316

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

Form: Visit Date

Generated On: 09 Jun 2021 16:31:58

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
User entered 'UNBLND_DECIDE'	System	05 Mar 2021 18:25:03

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:44:36
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered '4 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:27

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:03:51
User entered '0'	Dawn Killian (b) (4)	23 Apr 2021 07:38:04
Amendment Manager inserted this DataPoint.	(b) (4) System	06 Mar 2021 06:46:07

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:44:36
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:27

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
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 15:01:15
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 18:03:52
Query 'Per sponsor review, per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 07:38:15
User entered 'Amendment 6 or later (Amendment 6 or later)'	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 07:38:04
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 04:52:35
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 06:46:07

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:44:36
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered '4 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:27

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 19:44:36
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:27

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:44:36
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:27

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:44:36
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered 'mRNA-1273 (mRNA-1273)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:25:27

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:44:36
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User closed query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	(b) (4)	
	System	05 Mar 2021 18:25:31
Query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' answered by data change (Site from System).	System	05 Mar 2021 18:25:31
User entered 'No (N)' reason for change: Data Entry Error	Gerardo Pena (b) (4)	05 Mar 2021 18:25:31
	(b) (4)	
User opened query 'Actual dose 1 and Actual dose 2 are both recorded as mRNA-1273, however, 'Will participant receive mRNA-1273?' is Yes. Please reconcile.' (Site from System).	System	05 Mar 2021 18:25:27
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	05 Mar 2021 18:25:27
	(b) (4)	

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
User entered empty.	System	05 Mar 2021 18:25:27

US3292316

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

Form: Unblinding

Generated On: 09 Jun 2021 16:31:58

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
User entered empty.	System	05 Mar 2021 18:25:27

US3292316

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:39:57
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:26:02

US3292316

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.	(b) (4)	08 Apr 2021 19:39:57
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered '4 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:26:02

US3292316

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.	(b) (4)	08 Apr 2021 19:39:57
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered '15:50'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:26:02

US3292316

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 16:31:58

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
User entered '4 Mar 2021 15:50'	System	05 Mar 2021 18:26:02

US3292316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:31:58

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:45:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered 'Yes (Y)'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:26:13

US3292316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:31:58

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:45:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered '4 Mar 2021'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:26:13

US3292316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:31:58

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
DataPoint Verified.		08 Apr 2021 19:45:40
User signature succeeded.	Douglas Denham (b) (4)	05 Mar 2021 20:52:27
User entered '15:56'	(b) (4) Gerardo Pena (b) (4) (b) (4)	05 Mar 2021 18:26:13

US3292316

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 16:31:58

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 16:28:54
User entered '4 Mar 2021 15:56'	System	05 Mar 2021 18:26:13

US3292316

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 16:31:58

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:33
DataPoint Verified.		08 Apr 2021 17:46:42
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered 'Yes (Y)'	(b) (4) Nathan Cortez (b) (4)	09 Nov 2020 13:07:37

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:24:36
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Abscess limb, LLT: Foot abscess - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:50:40
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	10 Nov 2020 00:50:40
Data point term sent to Coder	System	09 Nov 2020 13:08:12
User entered 'L Foot Abcess'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:24:37
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:24:39
User entered 'No (N)'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:24:44
User entered 'No (N)'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Please confirm with source' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.		23 Mar 2021 18:07:30
Query 'Please confirm with source' answered with 'updated' (Site from CRA).		23 Mar 2021 18:07:29
User entered '11 Oct 2020' reason for change: Data Entry Error		20 Feb 2021 01:31:51
User opened query 'Please confirm with source' (Site from CRA).		20 Feb 2021 01:31:45
User entered '16 Oct 2020'	Nathan Cortez (b) (4)	29 Jan 2021 16:25:19
		09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:21
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User entered empty.	System	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:08
User entered 'No (N)' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	11 Nov 2020 22:36:36
User entered 'Yes (Y)'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:06
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	11 Nov 2020 22:36:36
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	11 Nov 2020 22:36:36
User entered '18 Oct 2020' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	11 Nov 2020 22:36:36
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	11 Nov 2020 22:35:25
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:22
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User entered empty.	System	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:24
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:25
User entered 'No (N)'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:34
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:37
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:38
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:40
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:42
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:51
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:53
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:55
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:25:56
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:06:42
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:26:18
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 22:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 22:35:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	11 Nov 2020 22:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:08:01
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:26:23
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 22:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 22:35:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	11 Nov 2020 22:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:08:01
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:26:34
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 22:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 22:35:25
User entered 'None (NONE)' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	11 Nov 2020 22:35:25
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:08:01
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:26:42
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	11 Nov 2020 22:35:25
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	09 Nov 2020 13:08:01
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:26:44
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		15 Dec 2020 10:25:13
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'updated meds' (Site from DM).	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:41:39
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 23:43:49
User entered 'I' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	11 Nov 2020 22:35:25
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:28:30
User entered '0'	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:28:31
User closed query 'Data is required. Please complete.' (Site from System).	System	11 Nov 2020 22:35:25
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	11 Nov 2020 22:35:25
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Gerardo Pena (b) (4) (b) (4)	11 Nov 2020 22:35:25
Data Entry Error		
User opened query 'Data is required. Please complete.' (Site from System).	System	09 Nov 2020 13:08:01
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:28:34
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:28:35
User entered empty.	Nathan Cortez (b) (4)	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User entered '0'	System	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37
User entered 'I'	System	09 Nov 2020 13:08:01

US3292316

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:49:37

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:55
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Oropharyngeal pain, LLT: Sore throat - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:28:48
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:28:48
Data point term sent to Coder	System	17 Dec 2020 18:28:11
User entered 'sore throat'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:57
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:31:59
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:02
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:06
User entered '12 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:07
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User entered empty.	System	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Please confirm with source' (Site from CRA).	(b) (4)	23 Mar 2021 18:09:39
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:08:10
Query 'Please confirm with source' answered with 'updated' (Site from CRA).		20 Feb 2021 01:33:56
User entered 'No (N)' reason for change: Data Entry Error		20 Feb 2021 01:33:49
User opened query 'Please confirm with source' (Site from CRA).		29 Jan 2021 16:31:43
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	17 Dec 2020 18:27:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Please confirm with source' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.		23 Mar 2021 18:09:41
Query 'Please confirm with source' answered with 'updated' (Site from CRA).		23 Mar 2021 18:08:08
User entered '18 Dec 2020' reason for change: Data Entry Error		20 Feb 2021 01:34:01
User opened query 'Please confirm with source' (Site from CRA).		20 Feb 2021 01:33:49
User entered empty.	Gerardo Pena (b) (4)	29 Jan 2021 16:31:51
	(b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:11
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User entered empty.	System	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:17
User entered 'Grade 1/Mild (Grade 1/Mild)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:19
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:21
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:22
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:24
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:26
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:27
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:29
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:31
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:34
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:36
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:32:38
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:27
User entered 'Not Related (NOT RELATED)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:30
User entered 'Not Related (NOT RELATED)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:38
User entered 'None (NONE)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:41
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Per CDM: Per previous query response "conmed updated"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 11:30:57
Query 'Per CDM: Per previous query response "conmed updated"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' answered with 'Patient used tylenol 325mg po prn. will add new line with this indication' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 19:38:20
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:33:48
User opened query 'Per CDM: Per previous query response "conmed updated"; however, the correction/update is not obvious please provide location of update such as the log line/form/data field updated. Thank you' (Site from DM).	(b) (4), (b) (6)	28 Jan 2021 10:55:38
User closed query 'Per DM CLR: Other Action Take = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		28 Jan 2021 10:55:38
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' answered with 'conmed updated' (Site from DM).		25 Jan 2021 18:50:11
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		14 Jan 2021 08:09:08

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User entered 'l'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:50
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Please confirm with source' (Site from CRA).	(b) (4)	23 Mar 2021 18:08:04
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:08:01
Query 'Please confirm with source' answered with 'updated' (Site from CRA).		20 Feb 2021 01:34:08
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:		20 Feb 2021 01:33:49
Data Entry Error		
User opened query 'Please confirm with source' (Site from CRA).		29 Jan 2021 16:31:37
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4)	17 Dec 2020 18:27:26
	(b) (4)	

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:52
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:33:58
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User entered '0'	System	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44
User entered 'I'	System	17 Dec 2020 18:27:26

US3292316

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:44

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Upper respiratory tract disorders (excl infections), HLT: Paranasal sinus disorders (excl infections and neoplasms), PT: Sinus congestion, LLT: Sinus congestion - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:33:45
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Dec 2020 18:33:45
Data point term sent to Coder	System	17 Dec 2020 18:32:17
User entered 'sinus congestion'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:23
User entered 'Yes (Y)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:25
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:29
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:34
User entered '12 Dec 2020'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:34:36
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User entered empty.	System	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Please confirm with source' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.		23 Mar 2021 18:10:20
Query 'Please confirm with source' answered with 'updated' (Site from CRA).		23 Mar 2021 18:10:14
User entered 'No (N)' reason for change: Data Entry Error		20 Feb 2021 01:35:19
User opened query 'Please confirm with source' (Site from CRA).		20 Feb 2021 01:35:08
User entered 'Yes (Y)'	Gerardo Pena (b) (4)	29 Jan 2021 16:34:48
	(b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Please confirm with source' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.		23 Mar 2021 18:10:24
Query 'Please confirm with source' answered with 'updated' (Site from CRA).		23 Mar 2021 18:10:18
User entered '15 Dec 2020' reason for change: Data Entry Error		20 Feb 2021 01:35:24
User opened query 'Please confirm with source' (Site from CRA).		20 Feb 2021 01:35:08
User entered empty.	Gerardo Pena (b) (4)	29 Jan 2021 16:34:53
	(b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:10:16
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User entered empty.	System	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:41:50
User entered 'Grade 1/Mild (Grade 1/Mild)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:41:52
User entered 'No (N)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:41:58
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:00
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:01
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:03
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:04
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:06
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:07
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:09
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:12
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:14
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:18
User entered 'Not Related (NOT RELATED)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:20
User entered 'Not Related (NOT RELATED)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:22
User entered 'None (NONE)'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:24
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:25
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	29 Jan 2021 09:29:52
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.'		25 Jan 2021 18:50:27
answered with 'conmed updated' (Site from DM).		
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no corresponding ConMed that match this AE during this time frame. Please update to record the corresponding ConMed treatment as appropriate. Otherwise, clarify.' (Site from DM).		14 Jan 2021 08:08:57
User entered 'l'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:27
User entered '0'	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Please confirm with source' (Site from CRA).	(b) (4)	23 Mar 2021 18:10:32
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:10:30
Query 'Please confirm with source' answered with 'updated' (Site from CRA).		20 Feb 2021 01:35:29
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:		20 Feb 2021 01:35:08
Data Entry Error		
User opened query 'Please confirm with source' (Site from CRA).		29 Jan 2021 16:35:01
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Gerardo Pena (b) (4)	17 Dec 2020 18:31:51
	(b) (4)	

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:28
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:42:40
User entered empty.	Gerardo Pena (b) (4) (b) (4)	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User entered '0'	System	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49
User entered 'I'	System	17 Dec 2020 18:31:51

US3292316

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:49

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:43:55
DataPoint Un-verified.	(b) (4), (b) (6)	29 Jan 2021 16:43:53
DataPoint Verified.		29 Jan 2021 16:43:52
Reviewed for Safety.		12 Jan 2021 19:00:29
User entered 'USA-US072-2021-mRNA-1273-P301000005'	System	12 Jan 2021 19:00:23
User entered 'New'	(b) (4), (b) (6)	12 Jan 2021 19:00:23

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:43:56
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Abscess limb, LLT: Gluteal abscess - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 19:07:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	12 Jan 2021 19:07:57
Data point term sent to Coder	System	11 Jan 2021 21:47:44
User entered 'Right Glute Abscess'	Antonio Gutierrez (b) (4) (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:43:58
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:02
User entered 'No (N)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:05
User entered 'No (N)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:09
User entered '3 Jan 2021'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:11
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	23 Mar 2021 18:11:05
DataPoint Un-verified.		20 Feb 2021 01:38:40
User entered 'No (N)' reason for change: Data Entry Error		20 Feb 2021 01:38:40
DataPoint Verified.		29 Jan 2021 16:44:12
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	23 Mar 2021 18:11:07
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).	(b) (4), (b) (6)	22 Feb 2021 18:34:49
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).		20 Feb 2021 01:38:59
User entered '25 Jan 2021' reason for change: Data Entry Error		20 Feb 2021 01:38:40
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).		19 Jan 2021 18:31:00
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:11:09
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:20
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:23
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:32
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:38
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:44:28
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).	(b) (4), (b) (6)	12 Jan 2021 13:49:55
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 still hospitalized. Admission date entered, patient not in ICU which is marked. ' (Site from System).	Antonio Gutierrez (b) (4)	11 Jan 2021 21:48:05
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	11 Jan 2021 21:47:14
User entered 'I'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Per AE source Comment , Subject was admitted to the hospital on 08Jan2021. Please review reconcile. ' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:08:09 21 Apr 2021 20:08:07
Query 'Per AE source Comment , Subject was admitted to the hospital on 08Jan2021. Please review reconcile. ' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	21 Apr 2021 18:53:16
User entered '08 Jan 2021' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	21 Apr 2021 18:53:01
User opened query 'Per AE source Comment , Subject was admitted to the hospital on 08Jan2021. Please review reconcile. ' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 21:12:06
User entered '09 Jan 2021' reason for change: New Information DataPoint Verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 22:33:29 08 Mar 2021 22:33:29
User entered '8 Jan 2021'	(b) (4), (b) (6)	29 Jan 2021 16:44:43
	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	19 Apr 2021 18:07:50
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).		09 Mar 2021 18:18:41
User closed query ' PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		09 Mar 2021 18:18:36
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 has been emailed to the address above.' (Site from Safety).	Antonio Gutierrez (b) (4)	08 Mar 2021 22:42:42
Query ' PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Antonio Gutierrez (b) (4)	08 Mar 2021 22:33:44
User entered '15 Jan 2021' reason for change: New Information	Antonio Gutierrez (b) (4)	08 Mar 2021 22:33:29
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)	19 Jan 2021 18:31:44
User opened query ' PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		19 Jan 2021 18:31:25
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:44:57
User entered 'No (N)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:45:02
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:45:03
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:45:05
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:45:06
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:45:18
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:45:21
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
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 in the narrative of the event, right glute abscess. ' (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 18:14:04
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 in the narrative of the event, right glute abscess. ' answered with 'updated' (Site from Safety). DataPoint Un-verified.	(b) (4), (b) (6) Antonio Gutierrez (b) (4)	21 Apr 2021 20:08:19 21 Apr 2021 18:53:24
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	21 Apr 2021 18:53:01
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 in the narrative of the event, right glute abscess. ' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:38:38
User closed query 'Per source, Action taken with study drug is "none"' (Site from CRA). DataPoint Verified.		08 Apr 2021 18:07:29 08 Apr 2021 18:07:27
Query 'Per source, Action taken with study drug is "none"' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	05 Apr 2021 21:51:54
User entered 'None (NONE)' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	05 Apr 2021 21:50:21
User opened query 'Per source, Action taken with study drug is "none"' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 18:12:34
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:45:57
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
Query 'PV Query: Please provide treatment given for the event, right glute abscess, 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.' canceled (Site from Safety). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Mar 2021 12:12:42
User opened query 'PV Query: Please provide treatment given for the event, right glute abscess, including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	29 Jan 2021 16:45:59
Query 'PV Query: Please provide treatment given for the event, diabetic ketoacidosis, 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)	19 Jan 2021 18:37:34
User opened query 'PV Query: Please provide treatment given for the event, diabetic ketoacidosis, 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)	19 Jan 2021 18:30:20
User entered 'I'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:46:00
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	23 Mar 2021 18:12:42
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)	22 Feb 2021 18:35:03
Query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'resolved' (Site from Safety).		20 Feb 2021 01:39:11
DataPoint Un-verified.		20 Feb 2021 01:38:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error		20 Feb 2021 01:38:40
DataPoint Verified.		29 Jan 2021 16:46:10
User opened query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		19 Jan 2021 18:30:49
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:46:14
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: SAE Narrative = DR. GAVE CEPHALEXIN 25 MG CAP 2 CAPS PO QID. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	26 Apr 2021 11:24:05
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, SHE GOT BACTRIM, IBUPROFEN, AND TYLENOL W CODEINE. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, SHE GOT BACTRIM, IBUPROFEN, AND TYLENOL W CODEINE. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	23 Apr 2021 06:38:59
User closed query 'Please consider whether there is an event of sepsis that meets SAE reporting criteria based on the hospital discharge summary which refers to sepsis secondary to perineal abscess.' (Site from Safety).		22 Apr 2021 20:21:20
Query 'Please consider whether there is an event of sepsis that meets SAE reporting criteria based on the hospital discharge summary which refers to sepsis secondary to perineal abscess.' answered with 'Does not meet SAE criteria, however AE added for Sepsis secondary to perineal abscess. ' (Site from Safety).		21 Apr 2021 20:38:43
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, SHE GOT BACTRIM, IBUPROFEN, AND TYLENOL W CODEINE. Please review and add a Con Medication as appropriate or update action taken.' answered with 'Added to conmed log. ' (Site from DM).		21 Apr 2021 20:09:18
Query 'Per DM CLR: SAE Narrative = DR. GAVE CEPHALEXIN 25 MG CAP 2 CAPS PO QID. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'Medication is added onto Conmed log (source) Pg 3.' (Site from DM).		21 Apr 2021 20:08:58

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Please consider whether there is an event of sepsis that meets SAE reporting criteria based on the hospital discharge summary which refers to sepsis secondary to perineal abscess.' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:02:15
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).		15 Mar 2021 12:12:34
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).		09 Mar 2021 18:19:08
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' answered with 'No testing noted in medical records' (Site from Safety).	Antonio Gutierrez (b) (4)	08 Mar 2021 22:46:21
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:46:25
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, SHE GOT BACTRIM, IBUPROFEN, AND TYLENOL W CODEINE. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		25 Jan 2021 00:15:56
User opened query 'Per DM CLR: SAE Narrative = DR. GAVE CEPHALEXIN 25 MG CAP 2 CAPS PO QID. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		25 Jan 2021 00:15:44

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
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).	(b) (4), (b) (6)	19 Jan 2021 18:30:06
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).		19 Jan 2021 18:29:46
User entered 'Per subject abscess is the size of a "softball" and there is potential she might require surgery for drainage, she will keep us updated.	Antonio Gutierrez (b) (4)	11 Jan 2021 21:47:14

Subject contacted and subject stated she had been admitted to the hospital on 08Jan2021 due to this abscess becoming infected. Subject is still in hospital at this time. Requesting medical records and reporting SAE

Subject reported that on 03Jan2021 a boil on buttock popped creating and an abscess, saw gynecologist on 06Jan2021, dr. gave cephalexin 25 mg cap 2 caps PO QID. Went to ER, Metropolitan Methodist on McCullough on 07Jan2021 because boil became larger and she got bactrim, ibuprofen, and tylenol w codeine. Skin started to peel and bleed and subject went to back ER on 08Jan2021 and was admitted. Gynecologist called subject with results of culture and culture concluded the infection was resistant to regular antibiotics, subject stopped oral antibiotics. Reporting SAE and requesting medical records from the hospital.'

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Jan 2021 21:47:14

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	23 Mar 2021 18:19:46
Reviewed for Safety.	(b) (4), (b) (6)	12 Jan 2021 19:01:01
User entered 'USA-US072-2021-mRNA-1273-P301000005'		12 Jan 2021 19:00:57

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:13
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Diabetic complications, HLT: Diabetic complications NEC, PT: Diabetic ketoacidosis, LLT: Diabetic ketoacidosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 22:12:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	11 Jan 2021 22:12:43
Data point term sent to Coder	System	11 Jan 2021 22:12:07
User entered 'Diabetic Ketoacidosis'	Antonio Gutierrez (b) (4) (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:14
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:18
User entered 'No (N)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:22
User entered 'No (N)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Please provide update to AE source.' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 16:50:54 22 Apr 2021 16:50:52
Query 'Please provide update to AE source.' answered with 'Updated.' (Site from CRA). User opened query 'Please provide update to AE source.' (Site from CRA). DataPoint Un-verified.		21 Apr 2021 20:39:15 16 Apr 2021 21:14:01 08 Apr 2021 19:50:55
DataPoint Verified.		08 Apr 2021 18:35:14
User closed query 'PV Query: Please confirm start date as DKA was discovered during hospitalization and the subject was not hospitalized until 09 Jan 2021.' (Site from Safety). Query 'PV Query: Please confirm start date as DKA was discovered during hospitalization and the subject was not hospitalized until 09 Jan 2021.' answered with 'Updated' (Site from Safety). DataPoint Un-verified.	Antonio Gutierrez (b) (4)	22 Mar 2021 15:17:41 19 Mar 2021 15:06:30 19 Mar 2021 15:05:24
User entered '09 Jan 2021' reason for change: Data Entry Error User opened query 'PV Query: Please confirm start date as DKA was discovered during hospitalization and the subject was not hospitalized until 09 Jan 2021.' (Site from Safety). DataPoint Verified.	Antonio Gutierrez (b) (4), (b) (6)	19 Mar 2021 15:05:24 16 Mar 2021 16:00:46 29 Jan 2021 16:47:29
User entered '8 Jan 2021'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:35
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Mar 2021 18:18:34
DataPoint Un-verified.	(b) (4), (b) (6)	20 Feb 2021 01:40:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	20 Feb 2021 01:40:15
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:47:32
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	23 Mar 2021 18:18:36
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).	(b) (4), (b) (6)	22 Feb 2021 18:35:36
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).		20 Feb 2021 01:40:23
DataPoint Un-verified.		20 Feb 2021 01:40:15
User entered '15 Jan 2021' reason for change: Data Entry Error		20 Feb 2021 01:40:15
DataPoint Verified.		11 Feb 2021 16:34:01
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).		19 Jan 2021 18:34:01
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:34:03
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:44
User entered 'Grade 3/Severe (Grade 3/Severe)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:47:45
User entered 'Yes (Y)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:34:16
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 16:34:28
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	29 Jan 2021 16:47:56
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).		12 Jan 2021 08:45:20
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 'Admission date present, no d/c date as patient is still hospitalized, "Admitted to ICU" already marked NO' (Site from System).	Antonio Gutierrez (b) (4)	11 Jan 2021 22:12:04
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	11 Jan 2021 22:11:25
User entered 'l'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
DataPoint Verified.	(b) (4)	30 Apr 2021 13:25:10
User closed query 'PV Query: Please confirm hospital admission date for the event, diabetic ketoacidosis as it is provided as 09 Jan 2021, and the event occurred while hospitalized for the other event, right glute abscess (admission date 08 Jan 2021). Please consider updating the admission date from 09 Jan 2021 to 08 Jan 2021 in the case narrative, as both admission dates are not in accordance. If not, please clarify.' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 21:06:46
Query 'PV Query: Please confirm hospital admission date for the event, diabetic ketoacidosis as it is provided as 09 Jan 2021, and the event occurred while hospitalized for the other event, right glute abscess (admission date 08 Jan 2021). Please consider updating the admission date from 09 Jan 2021 to 08 Jan 2021 in the case narrative, as both admission dates are not in accordance. If not, please clarify.' answered with 'updated to reflect correct admission date' (Site from Safety).	(b) (4), (b) (6)	29 Apr 2021 17:35:48
DataPoint Un-verified.		29 Apr 2021 17:35:13
Signature has been broken.		29 Apr 2021 17:35:13
User entered '8 Jan 2021' reason for change: Data Entry Error		29 Apr 2021 17:35:13
User opened query 'PV Query: Please confirm hospital admission date for the event, diabetic ketoacidosis as it is provided as 09 Jan 2021, and the event occurred while hospitalized for the other event, right glute abscess (admission date 08 Jan 2021). Please consider updating the admission date from 09 Jan 2021 to 08 Jan 2021 in the case narrative, as both admission dates are not in accordance. If not, please clarify.' (Site from Safety).		29 Apr 2021 13:39:29
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 20:25:10

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:49
User entered '9 Jan 2021' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:49
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:47:58
User entered '8 Jan 2021'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	08 Apr 2021 20:25:27
User closed query 'Per CDM: Please update when date becomes available. Thank you.' (Site from DM).	(b) (4), (b) (6)	22 Mar 2021 13:55:22
Query 'Per CDM: Please update when date becomes available. Thank you.' answered by data change (Site from DM).	System	19 Mar 2021 15:00:55
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	19 Mar 2021 15:00:55
User entered '15 Jan 2021' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	19 Mar 2021 15:00:55
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' canceled (Site from Safety).	(b) (4), (b) (6)	15 Mar 2021 12:13:02
Query 'PV Query: Please provide the hospital discharge date when available.' canceled (Site from Safety).		15 Mar 2021 12:12:57
DataPoint Verified.		11 Feb 2021 16:34:31
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).		19 Jan 2021 18:35:06
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		19 Jan 2021 18:34:53
User opened query 'Per CDM: Please update when date becomes available. Thank you.' (Site from DM).		12 Jan 2021 08:46:00
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:48:00
User entered 'No (N)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:48:02
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:48:03
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:48:05
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:48:06
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:48:13
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:48:14
User entered 'Not Related (NOT RELATED)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
Query 'Per source, action taken with study drug is "none" ' canceled (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:32:45
		08 Apr 2021 18:30:58
User opened query 'Per source, action taken with study drug is "none" ' (Site from CRA).		23 Mar 2021 18:19:26
User closed query 'Please confirm with source' (Site from CRA).		23 Mar 2021 18:19:26
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 in the narrative of the event, diabetic ketoacidosis.' (Site from Safety).		22 Mar 2021 15:17:47
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 in the narrative of the event, diabetic ketoacidosis.' answered with 'Updated' (Site from Safety).	Antonio Gutierrez (b) (4)	19 Mar 2021 15:02:59
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	19 Mar 2021 15:01:36
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 in the narrative of the event, diabetic ketoacidosis.' (Site from Safety).	(b) (4), (b) (6)	26 Feb 2021 04:41:30
Query '(AE #6) 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 in the narrative of the event, diabetic ketoacidosis.' canceled (Site from Safety).		26 Feb 2021 04:41:09
User opened query '(AE #6) 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 in the narrative of the event, diabetic ketoacidosis.' (Site from Safety).		26 Feb 2021 04:41:04
Query 'Please confirm with source' answered with 'updated' (Site from CRA).		20 Feb 2021 01:40:32
User entered 'None (NONE)' reason for change: Data Entry Error		20 Feb 2021 01:40:15

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User opened query 'Please confirm with source' (Site from CRA).	(b) (4), (b) (6)	29 Jan 2021 16:48:26
User entered 'Not Applicable (NOT APPLICABLE)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

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None

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 20:25:23
User closed query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).		2 Mar 2021 13:58:06
Query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' answered with 'Updated' (Site from DM).	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:21
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:05
User entered '0' reason for change: New Information	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:05
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:48:38
User opened query 'Per DM CLR: Serious= YES. However, there is no CM/ConProc recorded during the hospitalization period, and treatment is expected. Please review and ensure that CM/ConProc performed for this serious condition is added in the appropriate eCRFs. Update as applicable. Otherwise, provide comment for no treatment given. ' (Site from DM).		25 Jan 2021 00:16:23
User entered '1'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, Concomitant Procedure, however there is no Concomitant Medication or Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication and Con Procedure as appropriate or update action taken.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	26 Apr 2021 11:24:22
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, Concomitant Procedure, however there is no Concomitant Medication or Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication and Con Procedure as appropriate or update action taken.' answered with 'Conmed log updated.' (Site from DM). DataPoint Verified.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
	(b) (4), (b) (6)	21 Apr 2021 20:42:20
		08 Apr 2021 18:30:48
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, Concomitant Procedure, however there is no Concomitant Medication or Concomitant Procedure recorded that matches this AE during this timeframe. Please review and add a Con Medication and Con Procedure as appropriate or update action taken.' (Site from DM). DataPoint Un-verified.		05 Apr 2021 16:40:07
	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:05
User entered '1' reason for change: New Information	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:05
Query 'PV Query: Please provide treatment given for the event, diabetic ketoacidosis, 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.' canceled (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	15 Mar 2021 12:13:10
		29 Jan 2021 16:48:49

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event, diabetic ketoacidosis, 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)	19 Jan 2021 18:36:45
Query 'PV Query: Please provide treatment given for the event, diabetic ketoacidosis, 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.' canceled (Site from Safety).		19 Jan 2021 18:36:17
User opened query 'PV Query: Please provide treatment given for the event, diabetic ketoacidosis, 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).		19 Jan 2021 18:33:32
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:14:08
User entered '0' reason for change: New Information	Antonio Gutierrez (b) (4)	15 Apr 2021 16:47:05
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:05
User entered '1' reason for change: New Information	Antonio Gutierrez (b) (4)	19 Mar 2021 15:04:05
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:48:50
User entered '0'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	23 Mar 2021 18:27:14
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)	22 Feb 2021 18:35:59
Query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' answered with 'upodated (Site from Safety).		20 Feb 2021 01:40:38
DataPoint Un-verified.		20 Feb 2021 01:40:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:		20 Feb 2021 01:40:15
Data Entry Error		29 Jan 2021 16:48:52
DataPoint Verified.		19 Jan 2021 18:33:45
User opened query ' PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:48:54
Query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' canceled (Site from Safety).	(b) (4), (b) (6)	19 Jan 2021 18:34:30
User opened query 'PV Query: Please provide the final event outcome, when available. Please keep query open until resolution is achieved.' (Site from Safety).		19 Jan 2021 18:34:26
User entered empty.	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
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).	(b) (4), (b) (6)	15 Mar 2021 12:13:16
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.' canceled (Site from Safety).		15 Mar 2021 12:13:13
DataPoint Verified.		29 Jan 2021 16:49:00
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).		19 Jan 2021 18:33:11
User opened query ' PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing. If not done, please state so.' (Site from Safety).		19 Jan 2021 18:32:55
User entered 'DKA discovered while patient was hospitalized for an antibiotic-resistant gluteal abscess'	Antonio Gutierrez (b) (4)	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (6)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	11 Jan 2021 22:11:25

US3292316

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	11 Jan 2021 22:11:25

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Folder: Adverse Events

Form: Adverse Events (7)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09

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Folder: Adverse Events

Form: Adverse Events (7)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:49:21
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:55:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:55:57
Data point term sent to Coder	System	25 Jan 2021 18:55:15
User entered 'shortness of breath'	(b) (4), (b) (6)	25 Jan 2021 18:54:42

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:49:47
User entered 'Yes (Y)'		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:49:56
User entered 'No (N)'		25 Jan 2021 18:54:42

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Folder: Adverse Events

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:50:16
User entered 'No (N)'		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:50:20
User entered '15 Dec 2020'		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:50:22
User entered empty.		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User entered empty.	System	25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:51:02
User entered 'No (N)'		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:51:03
User entered '15 Dec 2020'		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:51:05
User entered empty.		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User entered empty.	System	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:51:07
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:51:12
User entered 'No (N)'		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:51:13
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:51:15
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:51:16
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:51:18
User entered empty.		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:51:22
User entered empty.		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:51:23
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:51:24
User entered empty.		25 Jan 2021 18:54:42

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Folder: Adverse Events

Form: Adverse Events (7)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:51:26
User entered '0'		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:53:59
User entered '0'		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:54:00
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:53:54
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:53:57
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:53:58
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 18:55:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 18:55:04
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 18:55:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 18:54:42
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:02
User entered 'l'		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:03
User entered '0'		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:54:05
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:14
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 18:55:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 18:55:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 18:55:04
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 18:54:42
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:54:16
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:18
User entered empty.		25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User entered '0'	System	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09
User entered 'I'	System	25 Jan 2021 18:54:42

US3292316

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:09

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:27
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Asthenic conditions, PT: Fatigue, LLT: Fatigue - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:56:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:56:50
Data point term sent to Coder	System	25 Jan 2021 18:56:16
User entered 'Fatigue'	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:54:29
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:54:31
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:36
User entered 'No (N)'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:38
User entered '15 Dec 2020'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:40
User entered empty.		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User entered empty.	System	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:42
User entered 'No (N)'		25 Jan 2021 18:56:12

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:54:45
User entered '15 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:46
User entered empty.		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User entered empty.	System	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:47
User entered 'Grade 1/Mild (Grade 1/Mild)'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:50
User entered 'No (N)'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:54:58
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:54:59
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:01
User entered '0'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:55:02
User entered empty.		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:05
User entered empty.		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:23
User entered empty.		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:25
User entered empty.		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:26
User entered '0'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:55:27
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:28
User entered '0'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:44
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:45
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:54:56
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 18:56:20
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 18:56:20
User entered 'None (NONE)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 18:56:20
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 18:56:12
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:47
User entered 'l'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:55:48
User entered '0'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:55:50
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:56:04
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:56:06
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:56:08
User entered empty.		25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User entered '0'	System	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12
User entered 'I'	System	25 Jan 2021 18:56:12

US3292316

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:12

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:05
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory tract signs and symptoms, HLT: Upper respiratory tract signs and symptoms, PT: Rhinorrhoea, LLT: Runny nose - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:58:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:58:55
Data point term sent to Coder	System	25 Jan 2021 18:58:18
User entered 'Runny nose'	(b) (4), (b) (6)	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:06
User entered 'Yes (Y)'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:07
User entered 'No (N)'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:09
User entered 'No (N)'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:10
User entered '15 Dec 2020' reason for change: Data Entry Error		25 Jan 2021 18:57:53
User entered '15 Jan 2021'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:11
User entered empty.		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User entered empty.	System	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:13
User entered 'No (N)'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:14
User closed query 'End date is prior to Start date. Please correct.' (Site from System).	System	25 Jan 2021 18:57:53
User opened query 'End date is prior to Start date. Please correct.' (Site from System).	System	25 Jan 2021 18:57:34
User entered '15 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:15
User entered empty.		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User entered empty.	System	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:57:18
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:20
User entered 'No (N)'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:21
User entered '0'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:23
User entered '0'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:57:24
User entered '0'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:02
User entered empty.		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:03
User entered empty.		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:58:04
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:06
User entered empty.		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:07
User entered '0'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:09
User entered '0'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:58:10
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:20
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:22
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:58:24
User entered 'None (NONE)'	(b) (4), (b) (6)	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:28
User entered 'l'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:31
User entered '0'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:33
User entered '0'		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:58:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:58:57
User entered empty.		25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:58:59
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User entered '0'	System	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33
User entered 'I'	System	25 Jan 2021 18:57:34

US3292316

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:33

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:08
User coded data point as SOC: General disorders and administration site conditions, HLGT: Body temperature conditions, HLT: Febrile disorders, PT: Pyrexia, LLT: Fever - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:59:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:59:58
Data point term sent to Coder	System	25 Jan 2021 18:59:18
User entered 'fever'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:10
User entered 'Yes (Y)'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:59:12
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:16
User entered 'No (N)'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:18
User entered '15 Dec 2020'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:19
User entered empty.		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User entered empty.	System	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:59:21
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:22
User entered '15 Dec 2020'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:24
User entered empty.		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User entered empty.	System	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:59:25
User entered 'Grade 1/Mild (Grade 1/Mild)'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:59:26
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:59:29
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:59:31
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 16:59:33
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:35
User entered empty.		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:36
User entered empty.		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:38
User entered empty.		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:39
User entered empty.		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:41
User entered '0'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:42
User entered '0'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:44
User entered '0'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:48
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:51
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 16:59:52
User entered 'None (NONE)'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Apr 2021 21:14:42
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:45:41
User entered '0' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	08 Mar 2021 18:45:41
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 16:59:58
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).		25 Jan 2021 18:59:23
User entered '1' reason for change: Data Entry Error		25 Jan 2021 18:59:23
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	25 Jan 2021 18:59:17
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Apr 2021 21:14:40
User closed query 'Per source, other action taken is "None".' (Site from CRA).		16 Apr 2021 21:14:38
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed #15 was started prior to the start date of this AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).		16 Apr 2021 09:37:05
Query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed #15 was started prior to the start date of this AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' answered with 'updated conmed log' (Site from DM).	Antonio Gutierrez (b) (4)	15 Apr 2021 14:45:27
Query 'Per source, other action taken is "None".' answered with 'source updated' (Site from CRA).	Antonio Gutierrez (b) (4)	15 Apr 2021 14:38:51
User opened query 'Per source, other action taken is "None".' (Site from CRA).	(b) (4), (b) (6)	23 Mar 2021 18:23:56
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed #15 was started prior to the start date of this AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).		22 Mar 2021 12:51:59
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:45:41
User entered '1' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	08 Mar 2021 18:45:41
DataPoint Verified.	(b) (4), (b) (6)	29 Jan 2021 17:00:01
User entered '0'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:00:05
User entered '0'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:00:07
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:00:10
User entered empty.		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:00:11
User entered empty.		25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User entered '0'	System	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39
User entered 'I'	System	25 Jan 2021 18:59:17

US3292316

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:39

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:00:23
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Sinusitis, LLT: Sinus infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:01:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Jan 2021 19:01:52
Data point term sent to Coder	System	25 Jan 2021 19:01:20
User entered 'Sinus Infection'	(b) (4), (b) (6)	25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:00:25
User entered 'Yes (Y)'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:00:28
User entered 'No (N)'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:29
User entered 'No (N)'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:31
User entered '13 Dec 2020'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 17:01:34
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User entered empty.	System	25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:36
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 19:01:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Jan 2021 19:01:10
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Jan 2021 19:01:10
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Jan 2021 19:00:55
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:38
User entered '18 Dec 2020' reason for change: Data Entry Error		25 Jan 2021 19:01:10
User entered '18 Jan 2021'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 17:01:40
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User entered empty.	System	25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:42
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:43
User entered 'No (N)'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:45
User entered '0'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:47
User entered '0'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:49
User entered '0'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:51
User entered empty.		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:52
User entered empty.		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:54
User entered empty.		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:56
User entered empty.		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 17:01:58
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:00:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:01:59
User entered '0'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:02:01
User entered '0'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:02:07
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:02:09
User entered 'Not Related (NOT RELATED)'		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:02:10
User entered 'None (NONE)'		25 Jan 2021 19:00:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:24:43
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).		22 Feb 2021 13:56:12
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Gerardo Pena (b) (4) (b) (4)	21 Feb 2021 19:27:01
DataPoint Un-verified.	Gerardo Pena (b) (4) (b) (4)	21 Feb 2021 19:26:56
User entered '0' reason for change: Data Entry Error	Gerardo Pena (b) (4) (b) (4)	21 Feb 2021 19:26:56
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	16 Feb 2021 11:31:19
DataPoint Verified.		29 Jan 2021 17:02:50
User entered '1'		25 Jan 2021 19:00:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Mar 2021 18:24:45
DataPoint Un-verified.	Gerardo Pena (b) (4)	21 Feb 2021 19:26:56
User entered '1' reason for change: Data Entry Error	(b) (4) Gerardo Pena (b) (4)	21 Feb 2021 19:26:56
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:02:51
User entered '0'		25 Jan 2021 19:00:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 17:02:52
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 19:00:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:02:57
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'		25 Jan 2021 19:00:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	29 Jan 2021 17:02:58
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 19:00:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Jan 2021 17:02:59
User entered empty.		25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User entered '0'	System	25 Jan 2021 19:00:55

US3292316

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48
User entered 'I'	System	25 Jan 2021 19:00:55

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:50:48

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Folder: Adverse Events

Form: Adverse Events (12)

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[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08

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Folder: Adverse Events

Form: Adverse Events (12)

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[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Sepsis, bacteraemia, viraemia and fungaemia NEC, PT: Sepsis, LLT: Sepsis secondary - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 16:12:55
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 16:12:55
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:19:36
Data point term sent to Coder		21 Apr 2021 20:36:48
User entered 'sepsis secondary to perineal abscess'		21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:19:34
User entered 'Yes (Y)'		21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:19:32
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:19:29
User entered 'No (N)'		21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:19:27
User entered '08 Mar 2021'		21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:19:25
User entered empty.		21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User entered empty.	System	21 Apr 2021 20:36:39

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Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:19:23
User entered 'No (N)'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:19:22
User entered '25 Mar 2021'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:19:20
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User entered empty.	System	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:19:19
User entered 'Grade 2/Moderate (Grade 2/Moderate)'		21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User closed query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' (Site from DM).		29 Apr 2021 09:40:53
Query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' answered with 'Does not meet SAE criteria. ' (Site from DM).		28 Apr 2021 20:36:28
User opened query 'Per MM, please confirm if this event does not meet serious criteria due to its medical significance.' (Site from DM).		27 Apr 2021 01:54:06
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 22:19:17
User entered 'No (N)'		21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:19:12
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:19:10
User entered '0'		21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:19:07
User entered '0'		21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:19:02
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:58
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:57
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:55
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:18:53
User entered '0'		21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:52
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Folder: Adverse Events

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:50
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:13:33
User closed query 'Per source, answer is not related. Please reconcile. ' (Site from CRA).		23 Apr 2021 15:13:31
Query 'Per source, answer is not related. Please reconcile. ' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	23 Apr 2021 07:42:04
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	23 Apr 2021 07:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 07:41:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Dawn Killian (b) (4)	23 Apr 2021 07:41:56
User opened query 'Per source, answer is not related. Please reconcile. ' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 22:18:00
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:36:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Folder: Adverse Events

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:13:36
User closed query 'Per source, answer is not related. Please reconcile. ' (Site from CRA).		23 Apr 2021 15:13:35
Query 'Per source, answer is not related. Please reconcile. ' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4)	23 Apr 2021 07:42:09
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	23 Apr 2021 07:41:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 07:41:56
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Dawn Killian (b) (4)	23 Apr 2021 07:41:56
User opened query 'Per source, answer is not related. Please reconcile. ' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 22:18:05
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:36:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:13:41
User closed query 'Per source, answer is none. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 15:13:39
Query 'Per source, answer is none. Please reconcile.' answered with 'updated' (Site from CRA).	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 07:42:32
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 07:42:23
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 07:42:23
User entered 'None (NONE)' reason for change: Data Entry Error	Dawn Killian (b) (4) (b) (4)	23 Apr 2021 07:42:23
User opened query 'Per source, answer is none. Please reconcile.' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 22:18:31
User opened query 'Data is required. Please complete.' (Site from System).	System	21 Apr 2021 20:36:39
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:33
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:34
User entered 'l'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:39
User entered '0'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:44
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4)	22 Apr 2021 22:18:46
User entered empty.	(b) (4), (b) (6)	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:18:47
User entered 'Per medical records, subject developed Sepsis (without shock) after developing a R glute Abscess. She was given Linezolid & Flagyl as treatment.'		21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User entered '0'	System	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08
User entered 'I'	System	21 Apr 2021 20:36:39

US3292316

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 16:31:58

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 11:51:08

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 16:31:58

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:33
DataPoint Verified.	(b) (4), (b) (6)	09 Apr 2021 20:20:46
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:11:44
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	27 Aug 2020 18:29:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:12:48
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:48:38
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:48:38
Data point term sent to Coder	System	27 Aug 2020 18:31:21
User entered 'IBUPROFEN'	(b) (4), (b) (6)	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:12:50
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:12:51
User entered 'HEADACHES'	(b) (4), (b) (6)	7 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Value does not match source. please review and reconcile.' (Site from CRA).	(b) (4)	08 Apr 2021 18:15:34
Query 'Value does not match source. please review and reconcile.' answered with 'source corrected to 800 as per medhx' (Site from CRA).	(b) (4), (b) (6)	
DataPoint Verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 17:58:38
	(b) (4), (b) (6)	10 Feb 2021 22:12:53
User opened query 'Value does not match source. please review and reconcile.' (Site from CRA).		10 Feb 2021 22:12:46
User entered '800'		27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:12:54
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:12:56
User entered empty.		27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:12:57
User entered 'as needed (PRN)'	(b) (4), (b) (6)	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:12:59
User entered empty.	(b) (4), (b) (6)	7 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:13:00
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:13:02
User entered empty.		27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:03
User entered 'UN UNK 1994'	(b) (4), (b) (6)	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:13:05
User entered '0'		27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:06
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:08
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:09
User entered 'No (N)'	(b) (4), (b) (6)	7 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 18:30:50

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:13:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 09:42:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 09:42:37
Data point term sent to Coder	System	27 Aug 2020 18:31:23
User entered 'Gabapentin'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:48
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:50
User entered 'DPN'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:51
User entered '1200'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:53
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:55
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:13:57
User entered 'three times daily (TID)'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:14:02
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:14:04
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:14:05
User entered empty.		27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:14:07
User entered 'un UNK 2015'		27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:14:09
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:14:13
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:14:17
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:14:20
User entered 'No (N)'		27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 18:31:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:14:29
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN DETEMIR, PRODUCTSYNONYM: LEVEMIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:48:44
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 19:48:44
Data point term sent to Coder	System	27 Aug 2020 18:32:26
User entered 'levemir'	(b) (4), (b) (6)	27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:14:31
User entered 'No (N)'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:14:32
User entered 'type II diabetes'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:14:37
User entered '35'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:14:38
User entered 'IU (IU)'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:14:39
User entered empty.		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:14:41
User entered 'once daily (QD)'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:14:43
User entered empty.		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:14:44
User entered 'Subcutaneous (SUBCUTANEOUS)'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:14:46
User entered empty.		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:14:52
User entered 'un UNK 2019'	(b) (4), (b) (6)	27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:14:53
User entered '0'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:14:54
User entered 'No (N)' reason for change: New Information		25 Jan 2021 18:31:55
User entered 'Yes (Y)'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:15:09
User entered '7 Jan 2021' reason for change: New Information		25 Jan 2021 18:31:55
User entered empty.		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:15:10
User entered 'No (N)'		27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User entered 'l'	System	27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User entered 'I'	System	27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:26
User entered '804 (804)'	System	27 Aug 2020 18:31:55

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:15:15
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:48:52
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 19:48:52
Data point term sent to Coder	System	27 Aug 2020 18:33:30
User entered 'levothyroxine'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:15:17
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:15:18
User entered 'hypothyroid'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:15:20
User entered '100'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:15:22
User entered 'ug (ug)'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:15:24
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:15:26
User entered 'once daily (QD)'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:15:31
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:15:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:15:36
User entered empty.		27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:15:47
User entered 'un UNK 1997'		27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:15:53
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:02
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:16:04
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:06
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	27 Aug 2020 18:32:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:16:13
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:48:53
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 19:48:53
Data point term sent to Coder	System	27 Aug 2020 18:33:31
User entered 'lorazepam'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:16
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:16:17
User entered 'anxiety'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:19
User entered 'l'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:21
User entered 'mg (mg)'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:23
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Feb 2021 22:16:39
User closed query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).		28 Nov 2020 18:05:07
Query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' answered with 'per patient this is correct' (Site from DM).	Dawn Killian (b) (4)	22 Sep 2020 21:26:28
User opened query 'Per DM CLR: Please review the Frequency as this medication is not typically administered as indicated. Please update the Frequency as appropriate.' (Site from DM).	(b) (4)	
User entered 'as needed (PRN)'	(b) (4), (b) (6)	22 Sep 2020 12:30:08
		27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:41
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:42
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:16:44
User entered empty.		27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:16:45
User entered 'un UNK 2017'		27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:47
User entered '0'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:48
User entered 'Yes (Y)'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:49
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:16:51
User entered 'No (N)'	(b) (4), (b) (6)	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	27 Aug 2020 18:33:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:17:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:49:02
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 19:49:02
Data point term sent to Coder	System	27 Aug 2020 18:34:33
User entered 'humalog'	(b) (4), (b) (6)	27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:17:21
User entered 'No (N)'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:17:22
User entered 'type II diabetes'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:17:23
User entered '60-100'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:17:25
User entered 'IU (IU)'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:17:26
User entered empty.		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	10 Feb 2021 22:17:28
User entered 'three times daily (TID)'	(b) (4), (b) (6)	27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:17:29
User entered empty.	(b) (4), (b) (6)	27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:17:30
User entered 'Subcutaneous (SUBCUTANEOUS)'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:17:32
User entered empty.		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:17:34
User entered 'un UNK 2019'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:17:35
User entered '0'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:17:37
User entered 'No (N)' reason for change: New Information		25 Jan 2021 18:30:26
User entered 'Yes (Y)'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4)
	(b) (4), (b) (6)	10 Feb 2021 22:17:41
User entered '7 Jan 2021' reason for change: New Information		25 Jan 2021 18:30:26
User entered empty.		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:18:34
User entered 'No (N)'		27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User entered '3'	System	27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User entered 'I'	System	27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:13
User entered '804 (804)'	System	27 Aug 2020 18:34:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:21:00
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANTIPSYCHOTICS, ATC: OTHER ANTIPSYCHOTICS, PRODUCT: RISPERIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:23:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Sep 2020 07:23:45
Data point term sent to Coder	System	27 Aug 2020 18:35:39
User entered 'risperidone'	(b) (4), (b) (6)	27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:21:02
User entered 'No (N)'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:21:05
User entered 'bipolar'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	10 Feb 2021 22:21:07
User entered '2'	(b) (4), (b) (6)	27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:21:08
User entered 'mg (mg)'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:21:10
User entered empty.		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:21:11
User entered 'once daily (QD)'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:21:13
User entered empty.		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:21:15
User entered 'Oral (ORAL)'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:21:16
User entered empty.		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:21:19
User entered 'un UNK 2017'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:21:21
User entered '0'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:21:23
User entered 'No (N)'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Feb 2021 22:21:26
User entered '30 Jun 2020'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 10 Feb 2021 22:21:27
User entered 'No (N)'		27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User entered 'l'	System	27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User entered 'I'	System	27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:17
User entered '804 (804)'	System	27 Aug 2020 18:35:15

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 08:30:00
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification. ' answered with 'no worsening in condition noted. ' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:22:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:17:50
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:17:50
Data point term sent to Coder	System	08 Mar 2021 18:16:33
Coding entries removed.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:15:56
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:44:43
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	16 Jan 2021 21:27:32

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 14:59:23
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 14:59:23
Data point term sent to Coder	System	04 Nov 2020 14:58:13
User entered 'Victoza'	(b) (4), (b) (6)	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:44:45
User entered 'No (N)'		04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:16:26
User closed query 'Please specify type of diabetes' (Site from CRA).		08 Apr 2021 18:16:24
Query 'Please specify type of diabetes' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:16:08
User entered 'Type II DIABETES' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:15:56
User opened query 'Please specify type of diabetes' (Site from CRA).	(b) (4), (b) (6)	11 Feb 2021 15:06:18
DataPoint Un-verified.		11 Feb 2021 15:05:54
DataPoint Verified.		11 Feb 2021 14:44:46
User entered 'Diabetes'		04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:44:48
User entered '0.6' reason for change: New Information	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:45:11
User entered '1.8' reason for change: New Information	Gerardo Pena (b) (4) (b) (4)	19 Nov 2020 22:16:41
User entered '0.6'	(b) (4), (b) (6)	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:16:57
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4)	10 Mar 2021 10:01:18
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:16:23
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:15:56
User entered 'mg (mg)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:15:56
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:44:56
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4), (b) (6)	16 Jan 2021 21:26:44
User entered 'mL (mL)'	(b) (4), (b) (6)	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:45:01
User entered empty.		04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:45:05
User entered 'once daily (QD)'		04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 14:45:06
User entered empty.	(b) (4), (b) (6)	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:17:19
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).		10 Mar 2021 10:04:05
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:16:33
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:15:56
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:15:56
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:45:07
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).		16 Jan 2021 21:27:19
User entered 'Intramuscular (INTRAMUSCULAR)'		04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4) (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:45:12
User entered empty.		04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 14:45:15
User entered '02 Nov 2020'	(b) (4), (b) (6)	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 14:45:16
User entered '0'	(b) (4), (b) (6)	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:45:22
User entered 'No (N)' reason for change: Data Entry Error	Dawn Killian (b) (4)	08 Dec 2020 18:45:11
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:45:23
User entered '16 Nov 2020' reason for change: Data Entry Error	Dawn Killian (b) (4)	08 Dec 2020 18:45:11
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:45:25
User entered 'No (N)'		04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User entered 'I'	System	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User entered 'I'	System	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:35
User entered '804 (804)'	System	04 Nov 2020 14:57:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:50:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 12:50:15
Data point term sent to Coder	System	08 Dec 2020 18:44:00
User entered 'sulfamethoxazole-trimethoprim'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:04
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:05
User entered 'left foot abscess'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:17:27
User closed query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4)	09 Mar 2021 08:29:41
Query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' answered with 'updated ' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:28:48
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:28:35
User entered '800/160' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:28:35
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:46:07
User opened query 'Per DM CLR: Please note, this is a combination drug; however, only one component has been reported in the dose field. Please update the dose to include both components as applicable (e.g., 500/125).' (Site from DM).	(b) (4)	02 Feb 2021 03:45:27
User entered '960'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:09
User entered 'mg (mg)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:11
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:12
User entered 'twice daily (BID)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:14
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:16
User entered 'Oral (ORAL)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:18
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:20
User entered '16 Oct 2020'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:21
User entered '0'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:23
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:25
User entered '20 Oct 2020'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:46:27
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User entered '2'	System	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User entered 'I'	System	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:39
User entered '804 (804)'	System	08 Dec 2020 18:43:09

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: SECOND-GENERATION CEPHALOSPORINS, PRODUCT: CEFUROXIME AXETIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 05:50:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 05:50:50
Data point term sent to Coder	System	08 Dec 2020 18:44:00
User entered 'cefuroxime axetil'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:29
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:30
User entered 'left foot abscess'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:32
User entered '250'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:34
User entered 'mg (mg)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:36
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:38
User entered 'twice daily (BID)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:39
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:41
User entered 'Oral (ORAL)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:42
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' answered with 'As per in-person patient report, this is correct as is.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 09:55:21
DataPoint Verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:37:41
User opened query 'Per DM CLR: Con Med start date is after the stop date of the corresponding AE. Please review and reconcile Con Med and AE start/stop dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:47:46
User entered '21 Oct 2020'	(b) (4)	02 Feb 2021 03:47:14
	Dawn Killian (b) (4)	08 Dec 2020 18:43:41
	(b) (4)	

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:47:48
User entered '0'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:18:58
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		09 Mar 2021 08:34:06
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:37:36
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:37:07
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	08 Mar 2021 18:37:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:47:55
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		02 Feb 2021 03:47:22
User entered 'Yes (Y)'	Dawn Killian (b) (4)	08 Dec 2020 18:43:41
	(b) (4)	

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:18:56
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:37:07
User entered '30 Oct 2020' reason for change: New Information	Antonio Gutierrez (b) (4)	08 Mar 2021 18:37:07
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:48:00
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:48:01
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User entered '2'	System	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User entered 'I'	System	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:49
User entered '804 (804)'	System	08 Dec 2020 18:43:41

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:27
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:45:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Dec 2020 18:45:51
Data point term sent to Coder	System	08 Dec 2020 18:45:01
User entered 'influenza vaccine'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:31
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:30
User entered 'influenza prophylaxis'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:33
User entered '0.5'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:34
User entered 'mL (mL)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:35
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:37
User entered 'once (ONCE)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:39
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:40
User entered 'Intramuscular (INTRAMUSCULAR)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:42
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:43
User entered '13 Oct 2020'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:45
User entered '0'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:46
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:48
User entered '13 Oct 2020'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:53:57
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User entered empty.	System	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User entered empty.	System	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:04:54
User entered empty.	System	08 Dec 2020 18:44:22

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new dose.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 08:34:32
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:24:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 18:24:40
Data point term sent to Coder	System	08 Mar 2021 18:23:39
Coding entries removed.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:23:33
Query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new dose.' answered with 'No worsening in condition noted. ' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:23:13
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:54:56
User opened query 'Per DM CLR: Was the dose of this medication increased because the patient experienced a worsening or exacerbation of the medical history condition/ adverse event being treated? If yes, please add the worsening AE and applicable data to the AE eCRF or provide explanation for addition of new dose.' (Site from DM).		02 Feb 2021 03:47:54

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 18:47:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Dec 2020 18:47:53
Data point term sent to Coder	System	08 Dec 2020 18:47:03
User entered 'victoza'	Dawn Killian (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:54:59
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:00
User entered 'type II diabetes'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:02
User entered '1.8'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:19:22
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:23:33
User entered 'mg (mg)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:23:33
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:55:04
User entered 'mL (mL)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:15
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:18
User entered 'once daily (QD)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:26
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:19:20
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).		09 Mar 2021 08:35:01
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:23:44
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:23:33
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:23:33
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:55:27
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	02 Feb 2021 03:47:42
User entered 'Intramuscular (INTRAMUSCULAR)'	Dawn Killian (b) (4)	08 Dec 2020 18:46:20
	(b) (4)	

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:30
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:34
User entered '17 Nov 2020'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:36
User entered '0'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:38
User entered 'Yes (Y)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:40
User entered empty.	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:55:42
User entered 'No (N)'	Dawn Killian (b) (4) (b) (4)	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Dec 2020 18:46:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:56:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: INTERMEDIATE-ACTING SULFONAMIDES, PRODUCT: SULFAMETHOXAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:25:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:25:02
Data point term sent to Coder	System	25 Jan 2021 18:36:55
User entered 'sulfamethoxazole'	(b) (4), (b) (6)	25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:56:56
User entered 'No (N)'		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Per DM CLR: Please review AE eCRF's AE #11 SINUS INFECTION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 08:42:15
User closed query 'Per CDM: Please review and confirm if this pertains to 'SINUS CONGESTION' (# 4) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 08:38:04
Query 'Per CDM: Please review and confirm if this pertains to 'SINUS CONGESTION' (# 4) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'does not pertain to congestion' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:41:29
Query 'Per DM CLR: Please review AE eCRF's AE #11 SINUS INFECTION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'already done' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:41:14
User opened query 'Per DM CLR: Please review AE eCRF's AE #11 SINUS INFECTION (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 09:59:49
DataPoint Verified.		11 Feb 2021 14:57:01
User opened query 'Per CDM: Please review and confirm if this pertains to 'SINUS CONGESTION' (# 4) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).		28 Jan 2021 10:59:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
User entered 'sinus infection'	(b) (4), (b) (6)	25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:11
User entered '800-160'		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:13
User entered 'mg (mg)'		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:14
User entered empty.		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:16
User entered 'twice daily (BID)'		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:18
User entered empty.		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:57:22
User entered 'Oral (ORAL)'		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:58:06
User entered empty.		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 14:58:11
User entered '13 Dec 2020'	(b) (4), (b) (6)	25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:58:13
User entered '0'		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:58:18
User entered 'No (N)'		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:58:20
User entered '15 Dec 2020'		25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:20:32
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).		09 Mar 2021 08:43:47
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:41:56
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:41:46
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:41:46
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 14:59:01
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).		27 Jan 2021 12:48:02

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User entered '2'	System	25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User entered 'I'	System	25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:03
User entered '804 (804)'	System	25 Jan 2021 18:36:05

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:16
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: MACROLIDES, PRODUCT: AZITHROMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:40:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:40:51
Data point term sent to Coder	System	25 Jan 2021 18:38:57
User entered 'azithromycin'	(b) (4), (b) (6)	25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:18
User entered 'No (N)'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Per CDM: Please review and confirm if this pertains to 'SINUS CONGESTION' (# 4) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4)	
Query 'Per CDM: Please review and confirm if this pertains to 'SINUS CONGESTION' (# 4) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' answered with 'does not pertain to congestion ' (Site from DM).	(b) (4), (b) (6)	09 Mar 2021 12:18:18
DataPoint Verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:42:23
User opened query 'Per CDM: Please review and confirm if this pertains to 'SINUS CONGESTION' (# 4) in the AE eCRF? If yes, please update to maintain consistency among eCRF pages.' (Site from DM).	(b) (4), (b) (6)	11 Feb 2021 14:59:19
User entered 'sinus infection'	(b) (4), (b) (6)	28 Jan 2021 10:59:28
	(b) (4), (b) (6)	25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:21
User entered '500'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:22
User entered 'mg (mg)'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:24
User entered empty.		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:34
User entered 'once daily (QD)'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:39
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:40
User entered 'Oral (ORAL)'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:45
User entered empty.		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:47
User entered '13 Dec 2020'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:49
User entered '0'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 14:59:51
User entered 'No (N)'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:00:02
User entered '17 Dec 2020'		25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:20:49
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).		09 Mar 2021 08:47:36
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:43:11
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:42:34
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:42:34
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:00:05
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).		27 Jan 2021 12:48:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User entered 'I'	System	25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User entered 'I'	System	25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:09
User entered '804 (804)'	System	25 Jan 2021 18:38:13

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:01
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)	25 Jan 2021 18:40:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 18:40:51
Data point term sent to Coder	System	25 Jan 2021 18:39:58
User entered 'tylenol'	(b) (4), (b) (6)	25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:03
User entered 'No (N)'		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Per DM CLR: Please review AE eCRF's AE #10 Fever (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 08:55:08
Query 'Per DM CLR: Please review AE eCRF's AE #10 Fever (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:46:08
User opened query 'Per DM CLR: Please review AE eCRF's AE #10 Fever (Other Action Taken=NONE); however, there is a con med associated with this condition. Please review and update AE eCRF's Other Action Taken to CONCOMITANT MEDICATION. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Feb 2021 10:00:22
DataPoint Verified.		11 Feb 2021 15:01:05
User entered 'fever'		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Dose amount does not match source. please review and reconcile.' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:21:16
		08 Apr 2021 18:21:13
Query 'Dose amount does not match source. please review and reconcile.' answered with 'updated' (Site from CRA).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:44:22
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:44:10
User entered '325' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:44:10
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:01:07
User opened query 'Dose amount does not match source. please review and reconcile.' (Site from CRA).		11 Feb 2021 15:00:59
User entered '500'		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:01:09
User entered 'mg (mg)'	(b) (4), (b) (6)	25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:10
User entered empty.		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:16
User entered 'as needed (PRN)'		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:17
User entered empty.		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:19
User entered 'Oral (ORAL)'		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:20
User entered empty.		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
DataPoint Verified.		21 Apr 2021 18:50:36
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Un-verified.	(b) (4)	
	Antonio Gutierrez (b) (4)	15 Apr 2021 14:44:55
User entered '15 Dec 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	15 Apr 2021 14:44:55
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:01:24
User entered '13 Dec 2020'		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:26
User entered '0'		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:27
User entered 'No (N)'		25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
DataPoint Verified.	(b) (4)	21 Apr 2021 18:50:37
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User closed query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 09:37:17
Query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' answered with 'updated as per query' (Site from DM).	Antonio Gutierrez (b) (4)	15 Apr 2021 14:45:05
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	15 Apr 2021 14:44:55
User entered '15 Dec 2020' reason for change: Per Query Resolution	Antonio Gutierrez (b) (4)	15 Apr 2021 14:44:55
User opened query 'Per DM CLR: Con Med stop date is after the stop date of the AE. It is not expected that this treatment would continue past the AE. Please review and reconcile Con Med and AE stop dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:03:02
DataPoint Verified.	(b) (4)	11 Feb 2021 15:01:30
User entered '17 Dec 2020'	(b) (4)	25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:01:31
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User entered empty.	System	25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User entered empty.	System	25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:15
User entered empty.	System	25 Jan 2021 18:39:26

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:55
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFALOXIN, PRODUCTSYNONYM: CEPHALOXIN [CEPHALOXIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 07:32:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 07:32:02
Data point term sent to Coder	System	25 Jan 2021 18:42:01
User entered 'cephalexin'	(b) (4), (b) (6)	25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:56
User entered 'Yes (Y)'		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:01:58
User entered 'Prophylaxis r glute abscess'	(b) (4), (b) (6)	25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:01:59
User entered '500'		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:01
User entered 'mg (mg)'		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:07
User entered empty.		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:02:08
User entered 'four times daily (QID)'	(b) (4), (b) (6)	25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:09
User entered empty.		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:11
User entered 'Oral (ORAL)'		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:12
User entered empty.		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:02:14
User entered '6 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:16
User entered '0'		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:18
User entered 'No (N)'		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:02:20
User entered '7 Jan 2021'		25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	08 Apr 2021 18:21:25
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Event for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).		09 Mar 2021 08:48:05
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:46:42
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:46:33
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:46:33
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:02:22
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).		27 Jan 2021 12:49:27

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User entered '4'	System	25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User entered 'I'	System	25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:22
User entered '804 (804)'	System	25 Jan 2021 18:41:01

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:00
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: OTHER ANTIBACTERIALS, PRODUCT: LINEZOLID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:00:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	26 Jan 2021 00:00:38
Data point term sent to Coder	System	25 Jan 2021 18:43:01
User entered 'linezolid'	(b) (4), (b) (6)	25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:02
User entered 'No (N)'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:04
User entered 'r glute abscess'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:05
User entered '600'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:07
User entered 'mg (mg)'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:09
User entered empty.		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:10
User entered 'twice daily (BID)'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:12
User entered empty.		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:14
User entered 'Oral (ORAL)'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:15
User entered empty.		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:17
User entered '16 Jan 2021'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:18
User entered '0'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:21:57
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	(b) (4) Antonio Gutierrez (b) (4)	09 Mar 2021 08:48:25 08 Mar 2021 19:04:04
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 19:03:57
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	08 Mar 2021 19:03:57
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 05:00:19
DataPoint Verified.		11 Feb 2021 15:03:20
User entered 'Yes (Y)'		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:22:15
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 19:03:57
User entered '25 Jan 2021' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 19:03:57
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:03:22
User entered empty.		25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	09 Apr 2021 20:22:58
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).	(b) (4), (b) (6)	-09 Mar 2021 08:55:40
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' answered with 'updated ' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 18:52:53
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 18:52:46
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 18:52:46
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:03:24
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).	(b) (4), (b) (6)	27 Jan 2021 12:49:47

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User entered 'Yes (Y)'	(b) (4), (b) (6)	25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User entered '2'	System	25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User entered 'I'	System	25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:28
User entered '804 (804)'	System	25 Jan 2021 18:42:18

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:50:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Jan 2021 23:50:58
Data point term sent to Coder	System	25 Jan 2021 18:44:02
User entered 'metronidozale'	(b) (4), (b) (6)	25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:03:35
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:37
User entered 'r glute abscess'		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:38
User entered '500'		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:40
User entered 'mg (mg)'		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:42
User entered empty.		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:43
User entered 'three times daily (TID)'		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:45
User entered empty.		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:47
User entered 'Oral (ORAL)'		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:49
User entered empty.		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:51
User entered '16 Jan 2021'		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:03:53
User entered '0'		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:22:25
User closed query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).		09 Mar 2021 08:53:15
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).		09 Mar 2021 08:52:35
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 19:05:08
Query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' answered with 'updated' (Site from DM).	Antonio Gutierrez (b) (4)	08 Mar 2021 19:04:59
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 19:04:40
User entered 'No (N)' reason for change: New Information	Antonio Gutierrez (b) (4)	08 Mar 2021 19:04:40

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 05:01:22
User opened query 'Per CDM: Was this medication taken for solicited event? = YES. However, the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body). Review and update eCRF as appropriate. Else clarify' (Site from DM).		11 Feb 2021 15:03:55
User entered 'Yes (Y)'		27 Jan 2021 12:50:06
		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:22:46
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 19:04:40
User entered '25 Jan 2021' reason for change: New Information	Antonio Gutierrez (b) (4)	08 Mar 2021 19:04:40
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:03:58
User entered empty.		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:22:49
DataPoint Un-verified.	Antonio Gutierrez (b) (4)	08 Mar 2021 19:04:40
User entered 'No (N)' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	08 Mar 2021 19:04:40
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:04:00
User entered 'Yes (Y)'		25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User entered '3'	System	25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User entered 'I'	System	25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:33
User entered '804 (804)'	System	25 Jan 2021 18:43:29

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:44:37
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:44:37
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	21 Apr 2021 20:43:59 21 Apr 2021 20:43:47
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:04:19
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, LONG-ACTING, PRODUCT: INSULIN GLARGINE, PRODUCTSYNONYM: LANTUS - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 18:47:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	25 Jan 2021 18:47:55
Data point term sent to Coder User entered 'Lantus'	System (b) (4), (b) (6)	25 Jan 2021 18:47:05 25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:21
User entered 'No (N)'		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:20:34
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:43:47
Signature has been broken.		21 Apr 2021 20:43:47
User entered 'DIABETEc ketoacidosis' reason for change: Per Query Resolution		21 Apr 2021 20:43:47
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:23
User entered 'Diabetes type II'		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:04:25
User entered '50'	(b) (4), (b) (6)	25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:27
User entered 'Other (OTHER)'		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:04:30
User entered 'unit'	(b) (4), (b) (6)	25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:04:32
User entered 'once daily (QD)'	(b) (4), (b) (6)	25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:35
User entered empty.		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:37
User entered 'Subcutaneous (SUBCUTANEOUS)'		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:39
User entered empty.		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:41
User entered '16 Jan 2021'		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:04:43
User entered '0'	(b) (4), (b) (6)	25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:44
User entered 'Yes (Y)'		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:46
User entered empty.		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:47
User entered 'No (N)'		25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'l'	System	25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 18:46:28

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:05:19
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 05:35:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 05:35:05
Data point term sent to Coder	System	21 Apr 2021 20:43:57
Coding entries removed.	(b) (4), (b) (6)	21 Apr 2021 20:43:16
DataPoint Un-verified.		21 Apr 2021 20:43:16
Coding entries removed.		21 Apr 2021 20:43:16
Signature has been broken.		21 Apr 2021 20:43:16
User entered 'Humalog' reason for change: Data Entry Error		21 Apr 2021 20:43:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4), (b) (6)	11 Feb 2021 15:04:54
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 18:48:55
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	25 Jan 2021 18:48:55
Data point term sent to Coder	System	25 Jan 2021 18:48:06

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'novolog'	(b) (4), (b) (6)	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:04:56
User entered 'No (N)'		25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 22:20:39
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
DataPoint Un-verified.	(b) (4)	21 Apr 2021 20:43:16
Signature has been broken.	(b) (4), (b) (6)	21 Apr 2021 20:43:16
User entered 'Diabetic ketoacidosis' reason for change: Data Entry Error		21 Apr 2021 20:43:16
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:04:58
User entered 'type 2 diabetes'	(b) (4), (b) (6)	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:05:06
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 15:05:04
DataPoint Verified.		11 Feb 2021 15:05:02
User entered '22'		25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:05:09
User entered 'Other (OTHER)'		25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:05:11
User entered 'unit'		25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:05:17
User entered 'three times daily (TID)'	(b) (4), (b) (6)	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:05:20
User entered empty.		25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:05:23
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4), (b) (6)	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:05:24
User entered empty.		25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:05:26
User entered '16 Jan 2021'	(b) (4), (b) (6)	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:05:33
DataPoint Un-verified.	(b) (4), (b) (6)	11 Feb 2021 15:05:31
DataPoint Verified.		11 Feb 2021 15:05:28
User entered '0'		25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Feb 2021 15:05:35
User entered 'Yes (Y)'		25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:05:37
User entered empty.	(b) (4), (b) (6)	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	11 Feb 2021 15:05:38
User entered 'No (N)'	(b) (4), (b) (6)	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	25 Jan 2021 18:47:43

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
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)	08 Mar 2021 19:41:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 19:41:40
Data point term sent to Coder	System	08 Mar 2021 19:40:26
User entered 'Tylenol'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered 'No (N)'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered 'Sore throat'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered '325'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered 'mg (mg)'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered empty.	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered 'as needed (PRN)'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered empty.	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered 'Oral (ORAL)'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered empty.	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered '12 Dec 2020'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered '0'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered 'No (N)'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered '18 Dec 2020'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:25:38
User entered 'No (N)'	Antonio Gutierrez (b) (4)	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User entered empty.	System	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User entered empty.	System	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:48
User entered empty.	System	08 Mar 2021 19:40:20

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.	(b) (4)	23 Apr 2021 15:09:18
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:38:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:38:52
Data point term sent to Coder	System	21 Apr 2021 20:11:00
User entered 'Ibuprofen'	(b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:20
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.		23 Apr 2021 15:09:21
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'R glute Abscess (SAE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
User signature succeeded.	Douglas Denham (b) (4)	28 Apr 2021 13:40:25
User closed query 'per source this is the dose for Bactrim. The dose for this medication is 600. Please update.' (Site from CRA).	(b) (4)	(b) (4), (b) (6)
DataPoint Verified.		23 Apr 2021 18:42:05
		23 Apr 2021 18:41:58
Query 'per source this is the dose for Bactrim. The dose for this medication is 600. Please update.'	Antonio Gutierrez (b) (4)	23 Apr 2021 18:39:22
answered with 'updated' (Site from CRA).		
Signature has been broken.	Antonio Gutierrez (b) (4)	23 Apr 2021 18:39:17
User entered '600' reason for change: Data Entry Error	Antonio Gutierrez (b) (4)	23 Apr 2021 18:39:17
User opened query 'per source this is the dose for Bactrim. The dose for this medication is 600. Please update.' (Site from CRA).	(b) (4), (b) (6)	23 Apr 2021 15:09:14
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '800/160'	(b) (4)	(b) (4), (b) (6)
		21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.		23 Apr 2021 15:09:23
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:25
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.	(b) (4)	23 Apr 2021 15:09:26
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'as needed (PRN)' reason for change:	(b) (4)	
Data Entry Error	(b) (4), (b) (6)	21 Apr 2021 20:11:53
User entered 'once daily (QD)'	(b) (4)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.		23 Apr 2021 15:09:29
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:35
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.		23 Apr 2021 15:09:39
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:38
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:40
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.		23 Apr 2021 15:09:42
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:09:43
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '09 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
DataPoint Verified.		23 Apr 2021 15:09:45
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
User entered empty.	System	21 Apr 2021 20:11:53
User entered '1'	System	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
User entered empty.	System	21 Apr 2021 20:11:53
User entered '1'	System	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:05:59
User entered empty.	System	21 Apr 2021 20:11:53
User entered '804 (804)'	System	21 Apr 2021 20:10:38

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.	(b) (4)	23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: SULFONAMIDES AND TRIMETHOPRIM, ATC: COMBINATIONS OF SULFONAMIDES AND TRIMETHOPRIM, INCL. DERIVATIVES, PRODUCT: SULFAMETHOXAZOLE;TRIMETHOPRIM, PRODUCTSYNONYM: BACTRIM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:12:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Apr 2021 20:12:46
Data point term sent to Coder	System	21 Apr 2021 20:12:02
User entered 'Bactrim'	(b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.		23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.		23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'R glute Abscess (sae)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.	(b) (4)	23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '800/160'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.	(b) (4)	23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.		23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.		23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.		23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.		23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.	(b) (4)	23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '09 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
DataPoint Verified.		23 Apr 2021 15:10:50
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
User entered 'I'	System	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
User entered 'I'	System	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:03
User entered '804 (804)'	System	21 Apr 2021 20:11:44

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.	(b) (4)	23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: CODEINE PHOSPHATE;PARACETAMOL, PRODUCTSYNONYM: TYLENOL W/CODEINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Apr 2021 07:17:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 07:17:55
Data point term sent to Coder	System	21 Apr 2021 20:13:03
User entered 'Tylenol w/ codeine'	(b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'R GLUTE ABSCESS PAIN'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '300/30'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.	(b) (4)	23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '07 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '0'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.		23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '09 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
DataPoint Verified.	(b) (4)	23 Apr 2021 15:10:52
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
User entered empty.	System	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
User entered empty.	System	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 16:31:58

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 05:06:10
User entered empty.	System	21 Apr 2021 20:12:57

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 16:31:58

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:13:33
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:54
User closed query 'Per SAE USA-US072-2021-MRNA-1273-P301000005, Con Procedures were done. Please update this page to yes and enter procedures as per med recs. If no procedures were done please amend AE/SAE forms to reflect as much.' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	22 Apr 2021 22:12:46
Query 'Per SAE USA-US072-2021-MRNA-1273-P301000005, Con Procedures were done. Please update this page to yes and enter procedures as per med recs. If no procedures were done please amend AE/SAE forms to reflect as much.' answered with 'Added.' (Site from CRA). DataPoint Un-verified.		22 Apr 2021 22:12:26
Signature has been broken.		21 Apr 2021 22:03:20
User entered 'Yes (Y)' reason for change: Data Entry Error DataPoint Verified.		21 Apr 2021 19:10:52
User opened query 'Per SAE USA-US072-2021-MRNA-1273-P301000005, Con Procedures were done. Please update this page to yes and enter procedures as per med recs. If no procedures were done please amend AE/SAE forms to reflect as much.' (Site from CRA). DataPoint Un-verified.		21 Apr 2021 19:10:52
DataPoint Verified.		09 Apr 2021 20:21:43
User signature succeeded.	Douglas Denham (b) (4)	08 Apr 2021 18:38:34
User entered 'No (N)'	(b) (4) Dawn Killian (b) (4) (b) (4)	08 Apr 2021 18:30:00
		08 Apr 2021 18:29:45
		23 Feb 2021 14:11:44
		04 Feb 2021 17:00:47

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:31:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:41
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '08 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:59:24

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:31:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:41
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'CT/ PELVIS'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:59:24

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:41
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:59:24

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 16:31:58

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:41
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:59:24

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:31:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:48
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '13 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:59:48

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:31:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:48
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'CHEST XRAY'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:59:48

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:48
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:59:48

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 16:31:58

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:48
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 21:59:48

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:31:58

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:51
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered '09 Jan 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:00:49

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:31:58

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:51
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'R GLUTE ABSCESS SURGICAL DEBRIDEMENT'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:00:49

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:31:58

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:51
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:00:49

US3292316

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 16:31:58

[If indication is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Apr 2021 13:55:51
User signature succeeded.	Douglas Denham (b) (4)	22 Apr 2021 15:51:23
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 22:00:49

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:31:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '12/Jan/2021 19:01'	(b) (4) System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 16:31:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'l'		12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:31:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered '22/Feb/2021 13:37'	(b) (4) System	22 Feb 2021 18:37:15

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 16:31:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 18:20:43
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
User entered 'l'	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:37:15

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:31:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:34:06
User entered '09/Mar/2021 13:20'	System	09 Mar 2021 18:21:00

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 16:31:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4)	08 Apr 2021 18:34:06
Reviewed for Safety.	(b) (4), (b) (6)	22 Mar 2021 15:18:29
User entered 'l'		09 Mar 2021 18:21:00

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:31:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:34:06
User entered '22/Mar/2021 10:18'	System	22 Mar 2021 15:18:42

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 16:31:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
Reviewed for Safety.	(b) (4)	15 Apr 2021 20:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User entered 'l'		22 Mar 2021 15:18:42

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:31:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	08 Apr 2021 18:34:06
User entered '06/Apr/2021 07:45'	System	06 Apr 2021 14:45:15

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 16:31:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
Reviewed for Safety.	(b) (4)	15 Apr 2021 20:00:32
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User entered 'l'		06 Apr 2021 14:45:15

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:31:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 17:59:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered '15/Apr/2021 16:00'	(b) (4) System	15 Apr 2021 20:00:46

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 16:31:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	22 Apr 2021 18:14:41
DataPoint Verified.		19 Apr 2021 17:59:02
User signature succeeded.	Douglas Denham (b) (4)	16 Apr 2021 14:41:48
User entered 'l'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 20:00:46

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:31:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:55
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:12:47
User entered '22/Apr/2021 14:15'	System	22 Apr 2021 18:15:07

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 16:31:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	23 Apr 2021 18:34:55
DataPoint Verified.	(b) (4)	23 Apr 2021 15:12:47
User entered 'l'	(b) (4), (b) (6)	22 Apr 2021 18:15:07

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'USA-US072-2021-MRNA-1273-P301000005'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Yes (Y)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'No (N)'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Douglas'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'Denham'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '7940 Floyd Curl Drive'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered 'San Antonio'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	12 Jan 2021 19:01:15
User entered '78229'	System	12 Jan 2021 19:00:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	08 Apr 2021 18:34:06
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	22 Feb 2021 18:36:44
User entered 'US'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 16:31:58

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '8'	System	29 Apr 2021 21:10:31
User entered '7'	System	22 Apr 2021 18:15:07
User entered '6'	System	15 Apr 2021 20:00:46
User entered '5'	System	06 Apr 2021 14:45:15
User entered '4'	System	22 Mar 2021 15:18:42
User entered '3'	System	09 Mar 2021 18:21:00
User signature succeeded.	Douglas Denham (b) (4)	23 Feb 2021 14:12:24
	(b) (4)	
User entered '2'	System	22 Feb 2021 18:37:15
User entered '1'	System	12 Jan 2021 19:01:23

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:31:58

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:25:29
User entered '29/Apr/2021 14:10'	System	29 Apr 2021 21:10:31

US3292316

Folder: SAE USA-US072-2021-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 16:31:58

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Douglas Denham (b) (4)	30 Apr 2021 14:50:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	30 Apr 2021 13:25:29
User entered 'I'		29 Apr 2021 21:10:31